2022

TROG CANCER RESEARCH

ANNUAL RESEARCH REPORT

Together, we can defeat cancer.

trog.com.au

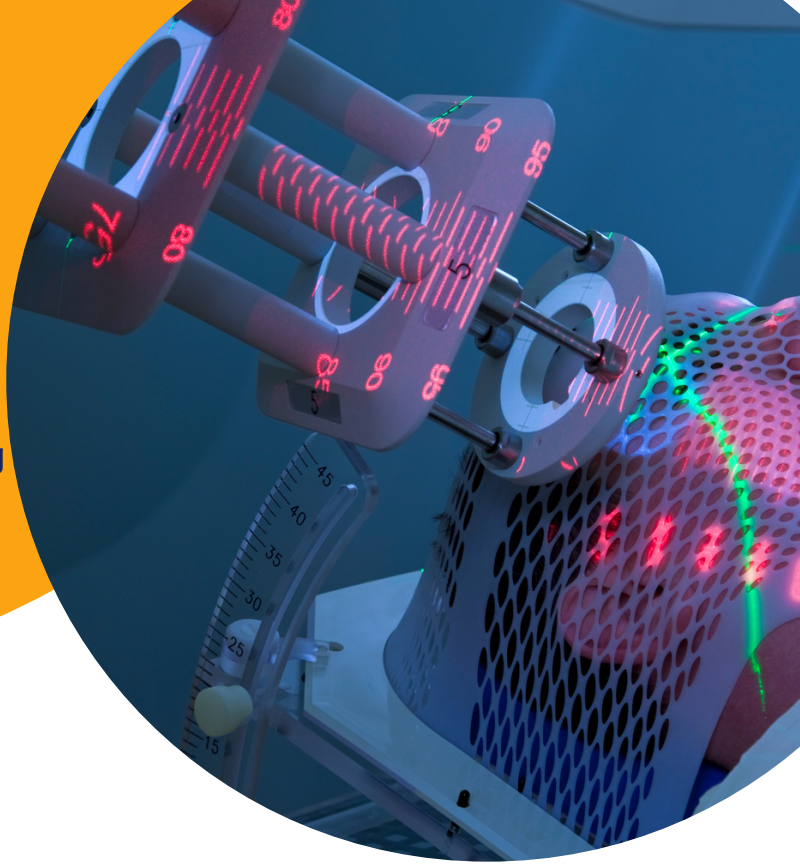
contents

Trans Tasman Radiation Oncology Group (TROG) 2022 Annual Research Report

our mission

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

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

Care:
We provide the utmost care and consideration to clinical trial participants. TROG Cancer Research 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.

Trans Tasman Radiation Oncology Group Limited
Australian Charities and Not-for-profits Commission
Registered charity
ABN:45132672292

about

TROG Cancer Research

TROG Cancer Research is dedicated to improving the way radiation therapy is delivered to cancer patients with ongoing scientific research, clinical trials, and cutting-edge technology.

TROG focuses on radiation medicine technology for all types of cancers that can be treated with radiation therapy, which like chemotherapy and surgery, it is widely used for cancer treatment. In fact, one-in-two patients diagnosed with cancer could benefit from radiation therapy.

Radiation therapy uses a controlled dose of radiation to kill cancer cells or damage them so they cannot grow, multiply or spread. The radiation is usually in the form of focused high energy radiation beams, with cutting edge research continually evolving and improving the techniques and technology used.

Trans Tasman Research Oncology Group (TROG) formed in 1989 when members of seven radiation therapy centres across Australia and New Zealand formed a clinical trials group to advance the study of cancers that could be treated with radiation therapy. Their vision was to improve outcomes of people affected by cancer through research in radiation therapy. To realise this vision, TROG collaborates with key stakeholders, organisations, and community groups with a shared aim of defeating cancer.

TROG has grown to be one of the largest collaborative clinical trials groups in Australia and New Zealand. The group works with its members, hospitals, universities, government agencies and other clinical trial groups to advance vital cancer research for the community.

34 *years active*

Over three decades, TROG has facilitated >115 clinical trials that contributed to improving outcomes and quality of life for >15,000 cancer patients globally. Over that time, the prognosis of cancer patients has improved with a cancer survival rate of less than 50 percent in the 1980s to survival rates for some cancers, being as high as 90 percent.

TROG conducts world-class research involving an international network of >1,500 health professionals and >100 sites, globally. Our trial portfolio encompasses research into all radiation treatable tumour sites. Research outcomes have led to changed clinical practice with new and improved radiation medicine techniques that can enhance outcomes for cancer patients.

All cancers: One treatment

TROG's research focus is on one type of treatment, radiation therapy, for the many types of cancers it can treat such as breast, lung, prostate, skin, head and neck.

Like chemotherapy and surgery, radiation therapy is a widely used cancer treatment. In fact, around 1 in 6 people will receive radiation therapy in their lifetime. Radiation therapy controls and even cures various cancers using high energy x-rays and similar rays, and cutting-edge research is continually improving techniques.

TROG Cancer Research

facts

>15,000 people have volunteered to participate in more than **>170** TROG trials since our inception.

>300 clinical trial committee volunteers providing >800 hours of time and valued service

12 % remote & regional sites

Telesite clinical trials participation

230 hospitals and cancer centres run TROG trials around the **WORLD**

TROG Cancer Research

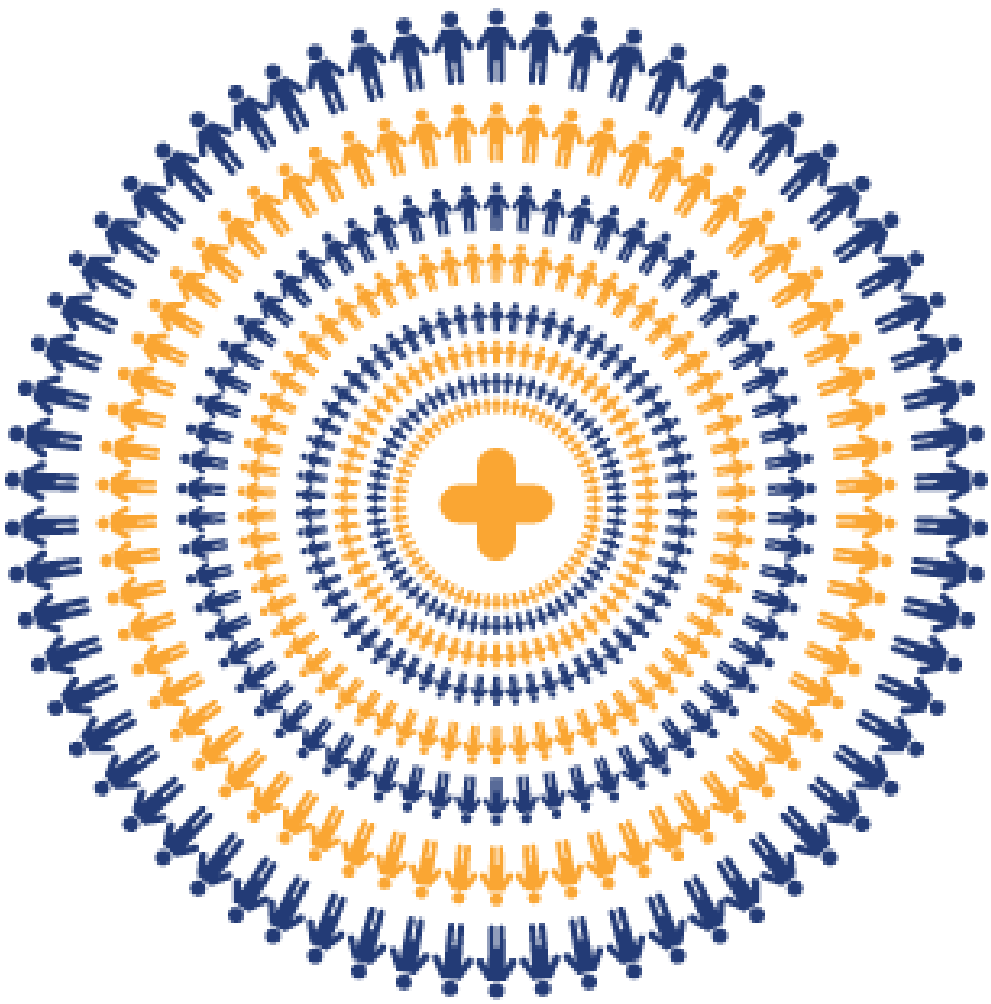
2022 snapshot

198 Full members

1443 Affiliate members

9 Life members

27 Facility Alliance Members



Collaborating organisations

- TOGA
- ANZUP
- AGIGT
- COGNO
- ANZGOG
- BCT
- MASC
- ARTnet
- GESA
- ICR
- EORTC
- BIG
- SCTG
- CCTG
- NCICCTG
- PoCoG
- USyd
- ANZGSA

13

Publications

14

Conference presentations

message from the President and Board Chair

Professor Trevor Leong

The past year has been a busy one for all at TROG Cancer Research. As we continue to adapt to the challenges of working in a COVID environment, it is pleasing to see that some aspects of our operations are returning to normal. We held our first face to face Annual Scientific Meeting (ASM) since 2019, and although we have convened several successful virtual meetings during the pandemic, I am sure you will agree that they do not capture the same sense of fun and camaraderie that is associated with in-person TROG meetings. The ASM was a wonderful opportunity to reconnect with friends and colleagues who we haven't seen for the past three years. I would like to thank the ASM convenors Sid Baxi, Hayley Brennan and David Willis, together with the Organising Committee for putting together a superb scientific program as well as an enjoyable social program. This year's meeting on the Gold Coast was well attended, and it is reassuring to see the Radiation Oncology community continuing to support TROG during these difficult times.

For the TROG Board, 2022 has been a particularly eventful year as we both farewelled and welcomed several new members. At the Annual General Meeting (AGM) in April, we farewelled two directors who have completed their terms on the Board. Rob Ferguson has been an Independent Consumer Representative Director since 2015, and Denis Byron has been an Independent Director since 2019. On behalf of TROG, I would like to thank them both for their tremendous contributions to the TROG Board. We have all benefited greatly from their experience, knowledge and wisdom. Also at this year's AGM we welcomed two additional Independent Directors, Andrew Beck and Murray McLachlan. Andrew works as a lawyer and Murray is an experienced patient advocate. I'm sure both will be valuable contributors to the TROG Board.

Dr. Keen Hun Tai completed his term on the Board as the Royal Australian and New Zealand College of Radiologists (RANZCR) FRO representative at the end of 2022, and I would like to thank him for his wise and thoughtful contributions to Board discussions. During Keen Hun's tenure, collaborations between TROG and RANZCR have strengthened. One example of this collaborative effort is the inaugural RANZCR-TROG Research Grant which was awarded for the first time in 2021.

Dr. Gerry Adams is the incoming Dean of RANZCR FRO, and as such will be appointed to the TROG Board. We look forward to working with Gerry.

I always begin our Board meetings by reminding Directors about TROG's vision, which is to "***Improve the outcomes of people affected by cancer through research in radiation medicine***." The current Strategic Plan for 2020-2023 has four key goals. Firstly, to "***lead a high impact clinical research portfolio***", which is the bread and butter of what we do. Secondly, to "***cultivate collaborations and partnerships***", which is particularly important in the current multidisciplinary environment of cancer research. Thirdly, to "***foster engagement and communication with our stakeholders***" including members, collaborators and funding bodies, and lastly, to "***build organisational capacity and sustainability***", which has been a particular focus of the Board in recent times.

Last year the Board implemented the Annual Board Strategic Planning Workshop to monitor our performance against the strategic plan, and enable the Board to respond to changes in the clinical research environment. I'm pleased to report that to date, movement towards goals set in our strategic plan has been progressing well.

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 Chief Executive Officer, TROG Scientific Committee Chair, and Financial and Risk Management Chair reports. Some of the highlights over the past 12 months include: successful Face to Face ASM with over 250 registrants; continuing trial activity with 29 open trials, 13 trials in development, and over 15,000 participants recruited over our thirty-year history; new investigator-initiated trials developed collaboratively with other Cancer Collaborative Trials Groups.

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 2022. I would also like to personally thank my fellow Board Directors for their guidance and friendship. We at TROG remain focussed on conducting high quality research that responds to patient needs, changes in cancer treatments, new technologies, the research environment, and our membership.

I look forward to seeing you all in 2023!

Prof. Trevor Leong

message from the Chief Executive Officer

Ms. Susan Goode

During 2022, TROG Cancer Research has continued to work towards achieving key goals within our 2020-2023 strategic plan. These key goals enable the conduct of world class radiation medicine research to control cancer that can lead to improve patient outcomes. The amazing achievement of recruiting our 15,000th TROG clinical trial participant could not have been made without the support of our staff, leadership, committee members, TROG members and mostly importantly, clinical trial participants and the community.

It was fantastic to be able to resume travel and face-to - face meetings with the easing of COVID related travel restrictions. Our TROG Annual Scientific Meeting (ASM) was held on the Gold Coast in a face-to-face format for the first time since 2019. This was a wonderful reunion for TROG members and industry partners, and a great delegate networking opportunity. Other face-to-face meetings included: the cancer collaborative trial group (CCTGs) meetings; several hospital and cancer treatment centre visits; and in November, our first in- person board meeting in three years.

Our TROG Central Operations Office (TCOO) team continues to work in a hybrid model, with flexible working arrangements helping the team to maintain a work-life balance whilst continuing to provide high level commitment and performance. We continue to develop TROG internal systems and infrastructure with the implementation of phase one of our Trial Management Database system. This system will assist and streamline processes for TROG clinical trials management, sites, institutions and personnel. In addition, scoping for system requirements to support the development of a new TROG Radiation Therapy and Imaging Clinical Quality Management System has also progressed.

In 2022, we continued to see a growing interest from our members and collaborators to undertake secondary data analysis projects. These projects utilise existing data sets from completed TROG clinical trials. The TCOO has put in place systems and processes to support our members to undertake secondary data analysis projects however, resourcing has constrained further progress in this area. To further increase collaborative research opportunities and to help relieve resourcing pressures, TROG has engaged in an Australian Research Data Commons funded partnership project with 13 other CCTGs, to increase the identification and access (findability) to clinical trial datasets. Additional funding opportunities are being explored by the TROG Secondary Data Analysis Committee whilst also embarking on reviews and refinement of TROG systems and processes.

Financial sustainability is an ongoing focus area and to aid the identification of TROG operational issues and potential risks, the TROG Management Team, in quarter four of 2022, conducted a wide reaching gap analysis of all TROG business activities. The outcomes of this identified areas for focus leading to the development of strategic action plans to be implemented in 2023.

Under the Clinical Trial Support Grant Scheme, TROG continues to work closely with Cancer Australia, with current activity and grant scheme being aligned with the national cancer plan and focusing on populations that have lower clinical trial participation, are hard to reach and have poorer cancer outcomes. These groups include: younger as well as older populations; participants in rural, regional and remote locations; culturally and linguistically diverse and first nation's populations. TROG is committed to improving access to clinical trials via a diverse clinical trial research portfolio which is representative of the populations that we serve.

Collaboration is the cornerstone of TROG and in 2022 we continued to grow in this space, partnering with organisation's and groups that share our vision to improve the outcomes for those affected by cancer. Our success in conducting world class radiation medicine research is underpinned by the contributions of our TROG team; including our expanding team of TROG staff, investigators, site staff, members and trial participants. I would like to personally thank you all for a wonderful 2022 and in 2023 we will continue our important work, making further advances in Radiation Oncology Research activity and outcomes.

Susan

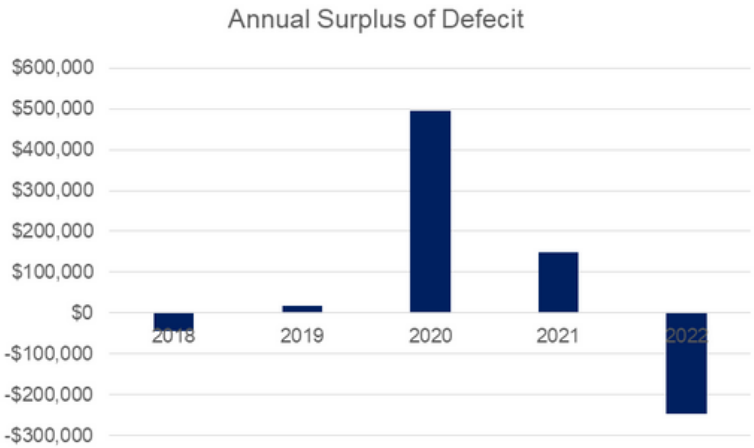
Doctor Tim Kuypers

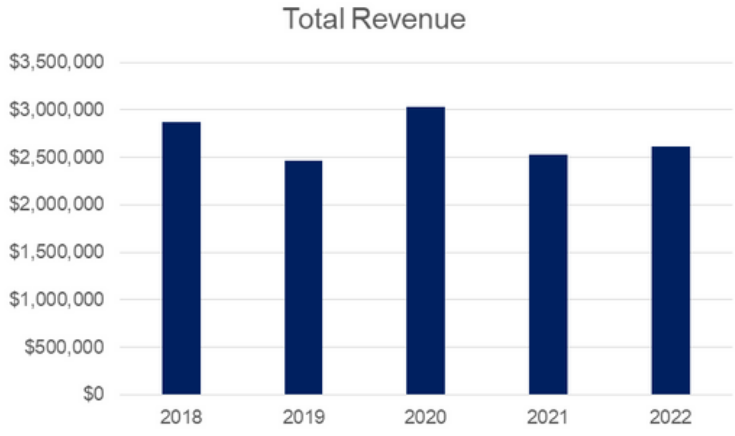
TROG Cancer Research delivered a deficit of $246,867 for 2022 in part due to post COVID cost pressures and underperforming trials.

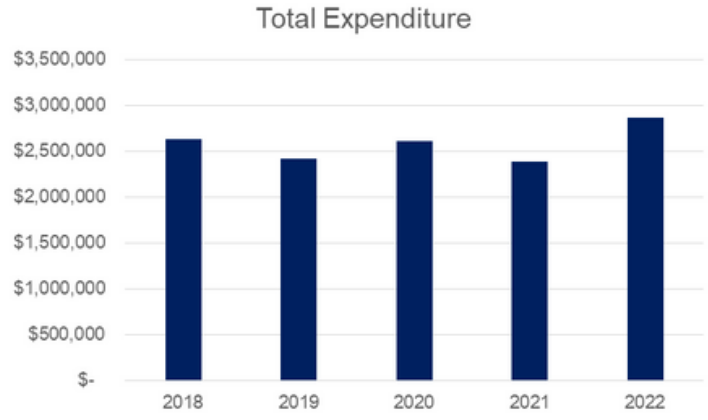
Revenue grew by 3.2% to $2.6m which was a strong result given government pandemic support dropped off and there was a material bequest included in 2021 revenue. Strong growth occurred in Annual Scientific Meeting (ASM) revenue as the ASM moved back to face to face. Both Radiation Therapy Quality Assurance (RTQA) and Research Services (RS) income grew but there was a reduction in donations and sponsorship revenue.

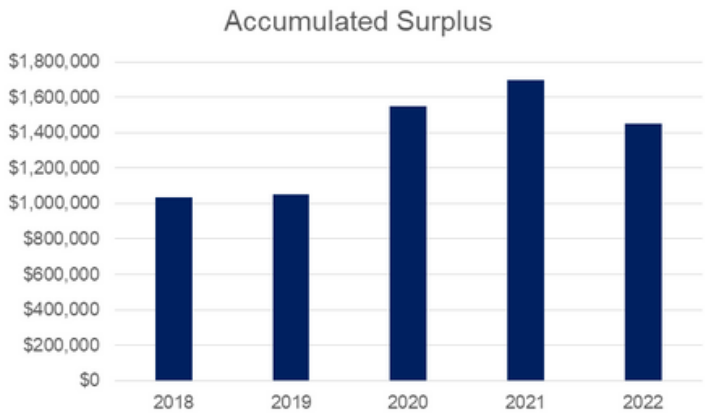
Cost increases in 2022 were large due to the ASM returning to face to face. This additional expense was more than covered by the increased ASM revenue. In kind expenses also increased. In kind expenses are the non-monetary contribution of software access utilised by RTQA and is matched with a corresponding increase in in-kind revenue. With an increase in full time equivalent staffing in the TROG central office, wages also increased, along with increases in computers & IT, but all other costs remained stable or reduced.

The deficit generated in 2022 reduced TROG's accumulated surplus (reserves for meeting future obligations and challenges). However, the reserves remain materially above pre pandemic levels.









message from the

Finance Audit & Risk Management Committee (FARM)

Doctor Tim Kuypers

The focus of the Finance Audit & Risk Management Committee (FARM) in 2022 returned to the efficiency of the core business post COVID. 2022 was a challenging year as COVID government support fell away.

The FARM, a subcommittee of the board, continued to assist management in understanding financial performance at an individual trial level. This granular focus allows the early identification of trials that are financially struggling and facilitates a mature discussion with investigators on the best ways to improve trial performance. In 2022 this approach has borne fruit, as two trials in particular were focussed on working collaboratively with the investigators and the financial performance of the trials were turned around. The trial level financial analysis also assists in pricing TROG Cancer Research's work and will provide a solid basis for improving fee for service financial performance in the coming years.

I would like to thank the TROG team for their efforts and hard work during another difficult and challenging year. I would also like to acknowledge my fellow FARM members and welcome the new members Andrew Beck and Sue Naeyaert and look forward to their ongoing input into TROG financial matters.

Dr. Tim Kuypers

FARM Members

Dr. Tim Kuypers, (Chairperson), Independent TROG Director
Dr. Fiona Hegi-Johnson, Radiation Oncologist
Mrs. Sue Naeyaert, Independent TROG Director
Mr. Andrew Beck, Independent TROG Director

message from the TROG Scientific Committee Chair

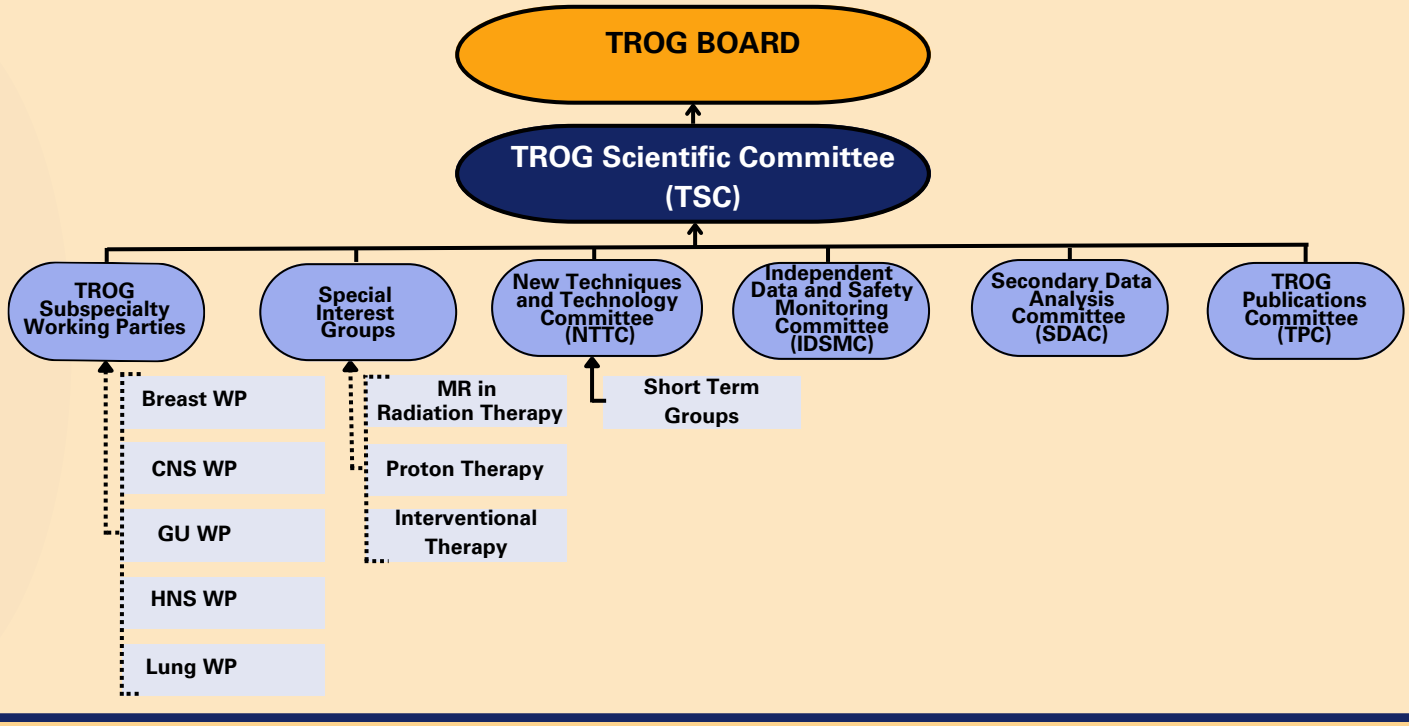
Associate Professor Sasha Senthi

What a year! TROG Cancer Research developed trials being awarded >$2.5 million in grant funding, moving back to a face-to-face Annual Scientific Meeting (ASM), recruitment of the 15,000th participant into a TROG trial, opening trials in new treatment areas, dissemination of results in high impact journals, collaboration in registry for rare cancers and TROG data used in multiple meta-analysis!

The TROG Scientific Committee (TSC) welcomed Dr. Lachlan MacDowell in June as new discipline representative for radiation oncology. Lachlan specialises in the treatment of head and neck cancers and his main research interests include clinical outcomes, health related quality of life and unmet needs in head and neck cancers. He participates on several international and national research committees, including as the current co-chair of the Head and Neck Cancer International Group's Young Investigator Committee, the deputy of the Guidelines and Protocols Committee, deputy chair of the TROG's Head and Neck and Skin Cancer Working Party and as a member of the scientific committee of the ANZ Head and Neck Cancer Society.

After four years as one of the three representatives for radiation oncology, Prof. Michael MacManus stepped down from the TSC in October. Specialising in lung cancer and haematological malignancies, Michael has led multiple TROG trials in lymphoma (TROG 99.03 and TROG 05.03) and published more than 100 journal articles and has more than 3900 citations of his work. I would like to thank Michael for his time, dedication and for sharing his expertise over the last four years, it has been truly appreciated.

Throughout 2022, TROG and the TSC has continued to work closely with our members to ensure that our trials and new proposals address the key priorities in radiation oncology and that we are horizon scanning for emerging technologies and techniques in radiation medicine. The TROG working parties are vital in shaping the research priorities of TROG by identifying gaps in research, developing new research concepts, reviewing the scientific merit of research proposals, and providing expert advice. Our tumour stream Working Parties are comprised of members from many craft groups and disciplines, with a focus on Head, Neck & Skin (HNS); Breast; Central Nervous System (CNS); Genitourinary (GU) and Lung cancers.



The working parties are complimented by several committees and special interest groups, who provide guidance to the TSC, those being

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

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

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, CNS, GU, HNS 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 the year brought.

Assoc Prof. Sasha Senthi

TROG Scientific Committee (TSC) Members

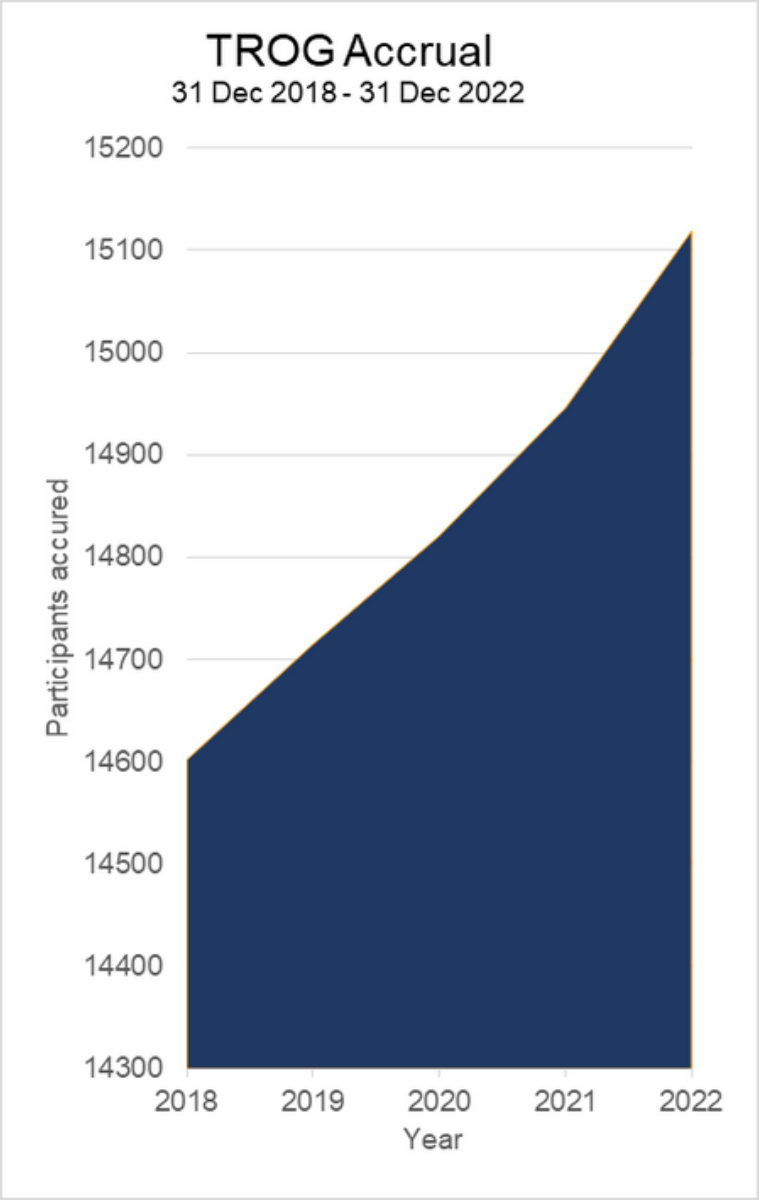
Assoc Prof. Sashendra Senthi, (Chairperson), Radiation Oncologist
Prof. Michael MacManus, Radiation Oncologist
Dr. Yoo Young (Dominique) Lee, Radiation Oncologist
Dr. Lachlan McDowell, Radiation Oncologist
Ms. Shivani Kumar, Radiation Therapist
Dr. James Lynam, Medical Oncologist
Dr. Jonathon Tibballls, Interventional Radiologist
Mr. Chris Brown, Statistician
Prof. Paul Keall, Medical Physicists
Mr. John Stubbs, Consumer
Assoc Prof. Richard De Abreu Lourenço, Health Economist
Assoc Prof. Brendan Mulhern, Health Economics and Outcomes Researcher
Ms. Renee Swanson, TROG Research Services Manager
Ms. Alisha Moore, TROG Radiation Therapy Manager

Ms. Rebecca Montgomery, (Secretariat), TROG Research Development Leader

our

2022 Highlights

173 participants were recruited into TROG Cancer Research lead trials in 2022. 15,119 people have helped TROG to achieve research results that change lives and improve outcomes and quality of life for those affected by cancer.



The 15,000th participant was recruited by the team at Calvary Mater Newcastle into the **TROG 19.06 DECREASE** (*DarolutamidE + Consolidation RadiothErapy in Advanced proStatE cancer detected by PSMA*) trial.

TROG 21.07 SOCRATES HCC (*A randomised controlled trial of Standard Of Care versus RadioAblaTion in Early Stage HepatoCelular Carcinoma*) was awarded Medical Research Future Fund (MRFF) funding in January. The first site was activated in October and recruitment of the first participant occurred in December. The study design includes the use of Interventional Radiology techniques - a first for TROG trials.
See page 57 for more details.

The **TROG 17.03 LARK** (*Liver Ablative Radiotherapy utilising Kilovoltage intrafraction monitoring (KIM)*) interim analysis was conducted, and the study has moved on to its second stage (inclusion of an additional five sites and 30 participant's). There have been multiple poster presentations at EPSM conference and Australasian College of Physical Scientists and Engineers in Medicine. sites and 30 participant's). There have been multiple poster presentations at EPSM conference and Australasian College of Physical Scientists and Engineers in Medicine.

We are excited to be a part of the **(TROG 21.12) ASPIRE Registry** (*Australian Particle Therapy Clinical Quality Registry*) designed to investigate patterns of care for participants receiving photon versus proton radiation treatment. ASPIRE will assist in describing the long-term effects and disease control outcomes for patients receiving radiation therapy as part of their cancer treatment.

Breast Working Party (BWP)

Prof. Boon Chua completed her final term as the inaugural chair of the Breast Working Party (BWP) in November 2022 and handed the reigns to Prof. Farshad Foroudi. On behalf of TROG Cancer Research, we thank Prof. Chua for her time, dedication, and leadership over the last four and a half years, it has truly been appreciated.

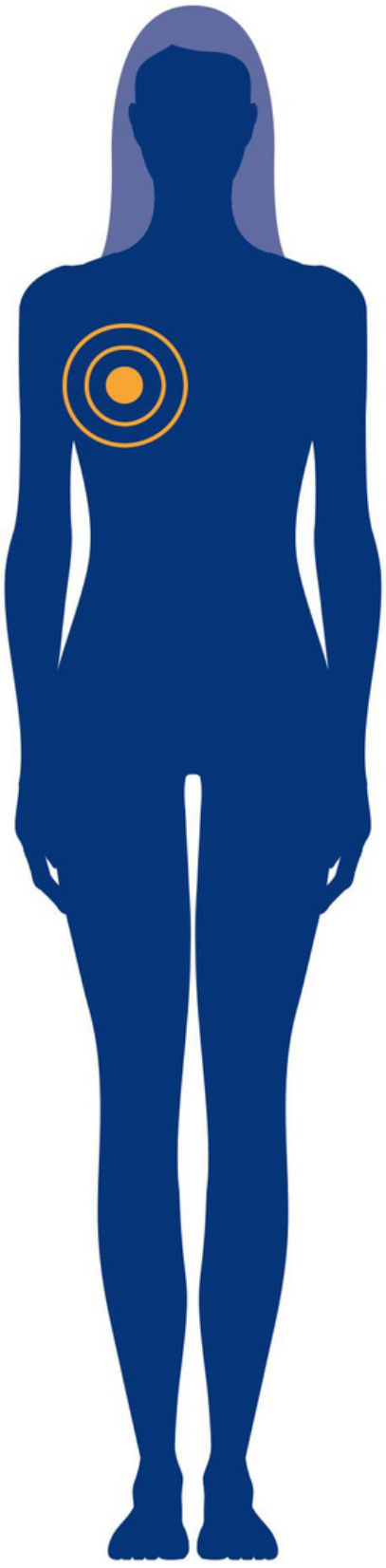
TROG 16.02 Local HER-O (*A phase II study of LOCAL therapy only (stereotactic radiosurgery and or surgery) for treatment of up to 5 brain metastases from HER2+ breast cancer*); all participants completed follow-up and data cleaning completed in preparation for analysis in 2023.

Results of **TROG 14.04 HART** (*Deep inHAlation breath hold for Reduction of cardiac Toxicity in patients with left sided breast cancer undergoing radiotherapy*) assessing the feasibility of deep inspiration breath hold (DIBH) and its impact on radiation dose to the heart in patients with left-sided breast cancer undergoing radiotherapy has been published. This study showed that although DIBH require about two min longer per treatment slot, it has the potential to reduce heart dose in left-sided breast cancer patients by nearly half, provided careful assessment of breath hold reproducibility is carried out.

A poster on **TROG 12.02 PET LABRADOR** (*PET scans for Locally Advanced BReast cancer And Diagnostic MRI to determine the extent of Operation and Radiotherapy*) was presented at the 2022 Australian International Breast Congress in October.

Findings from **TROG 07.01 DCIS** (*A randomised phase III study of radiation doses and fractionation schedules in non-low risk Ductal Carcinoma In-Situ of the breast*) has been recognised on a global scale in leading medical journal, The Lancet. This publication is a testament to the hard work, dedication and leadership of Prof. Boon Chua, the Chief Investigator and Study Chair, and the entire BIG 3-07/TROG 07.01 Trial team. We congratulate them on this important achievement. See page 41 for more details.

The BWP welcomed Dr. Steven David (RO), Jenna Dean (RT) and Dr. Chia May Wong (RO) as new members in 2022. Dr. Tao Mai (RO) has stepped down after four years on the working party – thank you for all your contribution to the TROG breast trial portfolio.



Breast WP members

Prof. Boon Chua, (Chairperson till Nov 2022), Radiation Oncologist
Assoc Prof. Farshad Foroudi, (Chairperson), Radiation Oncologist
Dr. Melissa James, Radiation Oncologist
Dr. Robyn Cheuk, Radiation Oncologist
Prof. Tomas Kron, Medical Physicist
Prof. Joerg Lehmann, Medical Physicist
Dr. Kylie Jung, Radiation Oncologist
Dr. Steven David, Radiation Oncologist
Ms. Jenna Dean, Radiation Therapist
Dr. Chia May Wong, Radiation Oncologist
Dr. Tao Mai, Radiation Oncologist

Genitourinary Working Party (GUWP)

TROG 18.01 NINJA (*Novel Integration of New prostate radiation schedules with adJuvant Androgen deprivation*) recruited its 200th participant – congratulations to the NINJA team for this milestone!

TROG 16.03 CORE (*A randomised trial of COnventional care versus Radioablation for Extracranial oligometastases*) and **(TROG 14.02) RAIDER** (*A Randomised phase II trial of Adaptive Image guided standard or Dose escalated Radiotherapy in the treatment of transitional cell carcinoma of the bladder*) both completed their primary analysis – results to come in 2023.

Data from **TROG 99.06** (*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*) and **TROG 03.01 RADAR** (*A Randomised phase III study in Advanced oesophageal carcinoma to compare Dysphagia in patients treated with Radiotherapy versus chemo-radiotherapy*) was included in two international meta-analysis that will have practice changing implications to the ADT treatment of men with prostate cancer receiving radiotherapy.

It was also fantastic to have Assoc Prof.Amar Kishan (Radiation Oncologist), lead author on both of these meta-analyses to present the findings at the TROG CAncer Research ASM in July 2022.

The results of a secondary analysis of the **TROG 08.03 RAVES** (*A phase III multi-centre randomised trial comparing adjuvant radiotherapy (RT) with early salvage RT in patients with positive margins or extra prostatic disease following radical prostatectomy*) dataset explored the potential of knowledge-based planning (KBP) as a powerful and efficient tool in clinical trials for quality assurance and planning purposes. The study showed that KBP was able to create treatment plans in less than five minutes that reduce radiation dose to the tumours surrounding organs, making it a powerful tool which should be utilised in clinical trials.

The GUWP welcomed Radiation Oncologists, Dr. Muhammad Ali and Dr. Nijula Thiru as new members in 2022. Ms. Kirrily Cloak (Radiation Therapy Project Manager), Prof.Jarad Martin (Radiation Oncologist) and Dr. Chris Wratten (Radiation Oncologist) stepped down from the committee and we would like to thank them for their four years on the working party, helping to shape the GU portfolio. years on the working party, helping to shape the GU portfolio.

Genitourinary WP members

Assoc Prof. Shankar Siva, (Chairperson), Radiation Oncologist
Dr. Stephen Chin (Deputy Chairperson), Radiation Oncologist
Ms. Alison Brown, Radiation Therapist
Dr. Charles Lin, Radiation Oncologist
Assoc Prof. David Pryor, Radiation Oncologist
Assoc Prof. Farshad Foroudi, Radiation Oncologist
Dr. Kristy Robledo, Biostatistician
Prof. Paul Keall, Medical Physicist
Dr. Robyn Cheuk, Radiation Oncologist
Dr. Wee Loon Ong, Radiation Oncologist
Dr. Muhammad Ali, Radiation Oncologist
Dr. Niluja Thiru, Radiation Oncologist
Ms. Kirrily Cloak, Radiation Therapy Project Manager
Prof.Jarad Martin, Radiation Oncologist
Dr. Chris Wratten, Radiation Oncologist

Central Nervous System Working Party (CNSWP)

The Central Nervous System (CNS) Working Party was hard at work in 2022, conducting gap analysis and developing trial ideas for the treatment of Radiation Necrosis, Brain Metastases and Meningiomas. The main idea under development is **TAILOR-BEV** (*Tailored Bevacizumab dose for symptomatic radiation necrosis after stereotactic radiosurgery for brain metastases.*)

The Working party has also supported multiple Category C trials:

- **BETTER** (*Bevacizumab and immune chEckpoint inhibitors plus hypofractionated stereotactic radioTherapy for the treatment of sympTomatic mElanoma bRain metastases*) led by ***MASC,*** *and*
- ***RT Prepare Mask*** *(Development and testing of a psycho education intervention for people requiring immobilisation masks during radiotherapy)* and led by **PoCoG**.

TROG 18.06 FIG (*Prospective, multicentre trial evaluating FET-PET In Glioblastoma*) recruitment increased by 280% in 2022. Congratulations to the FIG team for being awarded the Best Scientific Paper Presentation in Radiation Oncology and Best Scientific Paper at the RANZCR meeting in October. See page 59 for more details.

CNSWP was happy to welcome new members Dr. Alexandre Santos (MP) and Dr. Dionee Liefman (RO) in 2022. Dr. Sean Bydder (RO) has stepped down from the committee and we would like to say thank you for his support with establishing this important working party.

Central Nervous System WP members

Dr. Mark Pinkham,(Chairperson), Radiation Oncologist
Dr. Senthilkumar Gandhidasan, Radiation Oncologist
Dr. Andrew Pullar, Radiation Oncologist
Prof. Andrew Scott, Translational clinician-scientist
Dr. Claire Phillips, Radiation Oncologist
Assoc Prof. Eng-Siew Koh, Radiation Oncologist
Assoc Prof. Hien Le, Radiation Oncologist
Mr. John Ryan, Radiation Therapist
Dr. Kylie Jung, Radiation Oncologist
Dr. Sugun Parakh, Medical Oncologist
Dr. Wee Loon Ong, Radiation Oncologist
Prof. John Shakeshaft, Medical Physicist
Ms. Shona Edwards, Consumer
Dr. Alexandre Santos, Medical Physicist
Dr. Dionee Liefman, Radiation Oncologist
Prof. Michael McKay, Radiation Oncologist
Dr. Sean Bydder, Radiation Oncologist

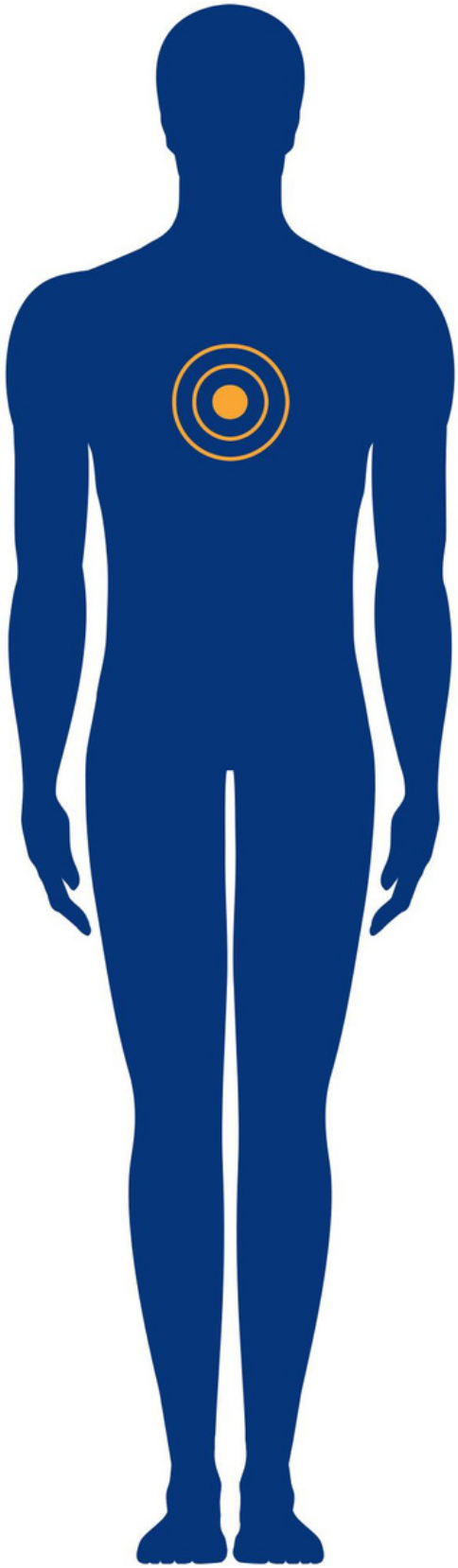
Lung Working Party (LWP)

TROG 20.01 CHEST RT (*A phase II study of platinum and etoposide CHemotherapy, durelumab with thoracic radiotherapy in the first line treatment of patients with Extensive-STage small-cell lung cancer*) recruited the first 20% of participants to the study in 2022. See page 58 for more information.

TROG 17.02 OUTRUN *(A randomised phase II trial of Osimertinib with or without stereotactic radiosurgery for EGFR mutated Non-Small Cell Lung Cancer (NSCLC) with brain metastases)* met its target sample size of 40 participants in September 2022. A prospective individual patient data meta-analysis with a similar Canadian trial (NCT03769103) has been planned. See page 60 for more information f

TROG 13.01 SAFRON II (*Stereotactic Ablative Fractionated Radiotherapy versus radiosurgery for Oligometastatic Neoplasia to the lung: A randomised phase II trial*) the cost-effectiveness substudy demonstrated that single fraction stereotactic ablative body radiation therapy (SABR) was potentially more cost-effective compared to multi-fraction SABR. This study finding was published in December 2022. See page 42 & 43 for more information.

Assoc Prof. Chee Lee (Med Onc) and Ms Kartina West (RT) stepped down form the LWP in 2022. We would like to thank both of them for their time and dedication to the group.



Lung WP members

Dr. Fiona Hegi-Johnson, (Chairperson), Radiation Oncologist
Dr. Yu Yang Soon, (Deputy Chairperson), Radiation Oncologist
Prof. Chee Lee, Medical Oncologist
Assoc Prof. Brett Hughes, Medical Oncologist
Prof. Michael MacManus, Radiation Oncologist
Dr. Tao Mai, Radiation Oncologist
Assoc Prof. Shalini Vinod, Radiation Oncologist
Prof. Tomas Kron, Medical Physicist
Dr. Eric Hau, Radiation Oncologist
Mr. Chris Brown, Biostatistician
Assoc Prof. Mark Pinkham, Radiation Oncologist
Dr. Jane Ludbrook, Radiation Oncologist
Prof. Margot Lehman, Radiation Oncologist
Dr. Sagun Parakh, Medical Oncologist
Dr. Wen Xu, Medical Oncologist
Ms. Katrina West, Radiation Therapist
Mrs. Susan Ann McCullough, Consumer

Head Neck and Skin Working Party (HNSWP)

TROG 12.01 HPV OROPHANYX (*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*) continued to disseminate its results with multiple publications. We are looking forward to results of the additional secondary analysis approved in 2022, including a cost analysis of Quality Assurance in Radiation Therapy.

(TROG 17.11) C-POST (*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*) continued recruitment in 2022 with Australia being the highest recruiting country internationally.

The HNSWP supported the Category C trial **RT Prepare Mask** (*Development and testing of a psycho education intervention for people requiring immobilisation masks during radiation therapy)* led by **PoCoG**.

We thank Dr. Wen Xu (Medical Oncologist) and Assoc Prof. David Kok (Radiation Oncologist) for their time on the HNS WP and welcome to Dr. Farhannah Aly (Radiation Oncologist), Mr. James Sandison (Radiation Therapist), Dr. Dionee Liefman (Radiation Oncologist) and Assoc Prof. Rahul Ladwa (Medical Oncologist) who have joined the working party in 2022.

Head Neck and Skin WP members

Dr. Charles Lin, (Chairperson), Radiation Oncologist
Dr. Lachlan McDowell, (Deputy Chairperson), Radiation Oncologist
Prof. June Corry, Radiation Oncologist
Dr. Andrew Macann, Radiation Oncologist
Dr. Thanuja Thachil, Radiation Oncologist
Assoc Prof. Brett Hughes, Medical Oncologist
Dr. Chris Wratten, Radiation Oncologist
Dr. Joe Chang, Radiation Oncologist
Assoc Prof. Siddhartha Baxi, Radiation Oncologist
Prof. Danny Rischin, Medical Oncologist
Dr. Tsien Fua, Radiation Oncologist
Dr. Margaret Chua, Radiation Oncologist
Prof. Sandro Porceddu, Radiation Oncologist
Assoc Prof. Ben Chua, Radiation Oncologist
Prof. Liz Kenny, Radiation Oncologist
Dr. Sweet Ping Ng, Radiation Oncologist
Dr. Albert Tiong, Radiation Oncologist
Dr. Howard Liu, Radiation Oncologist
Dr. Annette Lim, Medical Oncologist
Dr. Anzela Anzela, Radiation Oncologist
Dr. Daniel Xing, Radiation Oncologist
Dr. Farhannah Aly, Radiation Oncologist
Mr. James Sandison, Radiation Therapist
Dr. Dionee Liefman, Radiation Oncologist
Assoc Prof. Rahul Ladwa, Medical Oncologist
Dr. Wen Xu, Medical Oncologist
Assoc Prof. David Kok, Radiation Oncologist

Independent Data and Safety Monitoring Committee (IDSMC)

The TROG Cancer Research 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 TROG Scientific Committee (TSC), the IDSMC are responsible for making recommendations on the continuation of trials based on analysis from an ethical perspective, keeping and treating the rights, safety and welfare of participants first and foremost. The trial 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

Independent Data and Safety Monitoring Committee members

Prof. Bryan Burmeister, (Chairperson), Radiation Oncologist
Mrs. Peta Forder, Statistician
Prof. Michael Michael, Medical Oncologist
Assoc Prof. Guy Hingston, Surgical Oncologist
Dr. Nicholas Oddone-Baridon, Surgical Oncologist
Assoc Prof. Paul Nguyen, Radiation Oncologist

Ms. Wendy Paterson, Secretariat

Secondary Data Analysis Committee (SDAC)

Considerable resources – time, infrastructure, effort, intellectual energy – are invested by TROG Cancer Research and study investigators in collecting clinical trial data and ensuring those data are of exceptionally high quality. The result is a valuable resource and the TROG Secondary Data Analysis Committee (SDAC) has been working to ensure that resource is complete, accessible and being put to good use.

During 2022, the SDAC's activities in this regard included the following:

- Reviewing secondary analysis proposals.
- Reviewing TROG's secondary data analysis policy.
- Advising on the development of TROG's infrastructure for data acquisition, quality assurance and promotion including:

- continuing development of the Central Quality Management System (CQMS)
- Elekta ProKnow cloud-based data portal use
- addition of TROG as a node in the AusCAT distributed learning network
- TROG's contributions to the Health Studies Australian National Data Asset (HeSANDA) program via the "National Cancer Cooperative Trials Groups" HeSANDA node.

- Supporting the efforts of TROG office staff to make retrospective datasets useable and accessible, including through upload to Elekta ProKnow.
- Welcoming Ms. Tracey Pearl-Larsson to the committee.
- Joining a large collaboration of research and higher education institutions, professional bodies, industry partners and community groups to apply for infrastructure funds to develop a national cancer imaging network. This collaboration developed two major grant applications during 2022:

- MRFF 2021 Research Data Infrastructure grant opportunity (unsuccessful).
- MRFF 2022 Critical Research Infrastructure grant opportunity (unsuccessful).

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.

Secondary Data Analysis Committee members

Prof. Martin Ebert, (Chairperson), Medical Physicist
Dr. Sweet Ping Ng, Radiation Oncologist
Mr. Stuart Greenham, Radiation Therapist
Assoc Prof. Richard De Abreu Lourenco, Health Economist
Assoc Prof. Vanessa Panettieri, Medical Physicist
Mr. Kenton Thompson, Radiation Therapist
Prof. Val Gebski, Biostatistician
Mr. Michael Bailey, Medical Physicist
Assoc Prof. Lois Holloway, Medical Physicist
Ms. Tracy Pearl-Larsson, Clinical Trial Manager
Dr. Dionee Liefman, Radiation Oncologist
Ms. Renee Swanson, TROG Research Services Manager
Ms. Alisha Moore, TROG Radiation Therapy Manager

Ms. Sofee Holmes, (Secretariat),
TROG Quality Assurance Radiation Therapist

New Technologies & Techniques Committee (NTTC)

The New Technologies and Techniques Committee (NTTC) comprises medical physicists, radiation therapists and radiation oncologists as well as the TROG Cancer Research Radiation Therapy Manager. 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, CBCT-based 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.

The image registration group led by Assoc Prof. Nick Hardcastle has finalised its recommendations for the use of image registration in TROG trials and was endorsed by the TSC. A very large and active adaptive radiation therapy group led by Dr. Michael Jameson has been developing several policies and documents for this important new area including subgroups that are developing a facility questionnaire, radiation therapy guidelines, and technical frameworks. It is very encouraging to see these sub-groups lead so superbly by younger emerging leaders in our radiation oncology community. Work is also ongoing on a new updated overarching facility questionnaire with special techniques as additional modules.

A policy for minimum requirements for independent dosimetric audits in TROG clinical trials has been developed and is expected to be endorsed in 2023. This will ensure that external bodies conducting dosimetric audits clearly understand what is required to demonstrate that they fulfil TROG auditing requirements. Considerations on credentialling of satellite sites is ongoing. This is a difficult area and will require careful consideration to make an evidence-based decision. A manuscript on the Sensitivity assessment system to improve quality in Radiation Oncology treatments (SEAFARER) audit of pre-treatment Quality Assurance procedures has been published in Radiation Oncology, and a Cancer Australia grant awarded to apply the audit to centres throughout Australia. A postdoctoral researcher is currently developing the tools and plans required for this study. The Virtual EPID Standard Phantom Audit (VESPA) remote auditing program has continued with auditing of international centres for participation in TROG trials with approximately one audit per month including centres in Canada, Taiwan, UK, Spain and Switzerland and more recently Africa for their own hypo-fractionation trial. Conference abstracts have been submitted and a VESPA article is expected to be published in the Journal of Physics and Medicine in Biology in early 2023.

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.
In 2023 Prof. Peter Greer will step down from the role of Chair of the Committee after six years at the helm and Assoc Prof. Nick Hardcastle has kindly agreed to take over as Chairperson. Peter has been an incredible asset to the committee providing leadership and support as well as both research and technical expertise. We are delighted to have Peter remain on the Committee as a valuable contributing member. In 2023, we look forward to welcoming Nick, who will bring considerable clinical and research experience and his active involvement in many clinical trials and studies to the table ensuring a strong and relevant committee for the future.

New Technologies & Techniques Committee (NTTC) members

Prof. Peter Greer, (Chairperson), Medical Physicist
Assoc Prof. Nick Hardcastle, Medical Physicist
Mr. Michael Bailey, Medical Physicist
Prof. Annette Haworth, Medical Physicist
Prof. Tomas Kron, Medical Physicist
Prof. Joerg Lehmann, Medical Physicist
Mr. Rob McDowall, Radiation Therapist
Mr. Kenton Thompson, Radiation Therapist
Dr. John Shakeshaft, Medical Physicist
Dr. Andrew Cousins, Medical Physicist
Dr. Michael Jameson, Medical Physicist
Prof. Martin Ebert, Medical Physicist
Assoc Prof. Rhonda Brown, Medical Physicist
Assoc Prof. Farshad Foroudi, Radiation Oncologist
Mr. David Willis, Radiation Therapist
Dr. Ben Hindson, Radiation Oncologist
Mr. Dean Wilkinson, Medical Physicist
Ms. Angela Whitehead,
TROG Radiation Quality Assurance Therapist
Ms. Patricia Banyer,
TROG Radiation Quality Assurance Therapist
Ms. Olivia Cook,
TROG Radiation Quality Assurance Therapist
Ms. Alana Rossi,
TROG Radiation Quality Assurance Therapist
Ms. Sofee Holmes,
TROG Radiation Quality Assurance Therapist
Ms. Alisha Moore,
TROG Radiation Therapy Manager

TROG Publications Committee (TPC)

We are proud to have over 260 publications attributed to TROG Cancer Research, with 13 published in 2022. (See following pages 27 & 28 for details).

Three TPC meetings were held in 2022. 10 publications were reviewed by the committee: Five Category A, one Category B, and four Category C, with all manuscripts acknowledging TROG appropriately. We thank all of these authors for continuing to ensure TROG receives this appropriate acknowledgement.

The TROG Authorship, Publication, and Spokesperson guideline remains available to all TROG members via the TROG website's members area providing guidance for investigators and authors regarding publication of TROG clinical trial results.

Guideline link

Any publication arising from the analysis of the data from a TROG trial is expected to be submitted to the TPC prior to publications.

Contact publications@trog.com.au for more information.

We are looking forward to a busy 2023 with several TROG trials nearing data maturity time-points.

TROG Publications Committee members

Dr. Shivani Kumar, (Chairperson), Radiation Therapist
Assoc Prof. Sashendra Senthi, Radiation Oncologist
Mr. Chris Brown, Biostatistician

Dr. Ryan Davey, (Secretariat), TROG Clinical Research Associate

our

2022 TROG Publications

TRIAL OUTCOMES

TROG led studies

TROG 14.04 HART

Kron T, Bressel M, Lonski P, Hill C, Mercieca-Bebber R, Ahern V, Lehman M, Johnson C, Latty D, Ward R, Miller D, Banjade D, Morriss D, De Abreu Lourenco R, Woodcock J, Montgomery R, Lehmann J, Chua BH. TROG 14.04: Multicentre Study of Feasibility and Impact on Anxiety of DIBH in Breast Cancer Patients. Clin Oncol (R Coll Radiol). 2022 Sep;34(9):e410-e419. doi: 10.1016/j.clon.2022.05.020. Epub 2022 Jun 16. PMID: 35717318.

TROG 13.01 SAFRON II

Lourenco RA, Khoo T, Crothers A, Haas M, Montgomery R, Ball D, Bressel M, Siva S. Cost-Effectiveness of Single Versus Multifraction SABR for Pulmonary Oligometastases: The SAFRON II Trial. Int J Radiat Oncol Biol Phys. 2022 Dec 1;114(5):968-976. doi: 10.1016/j.ijrobp.2022.01.024. Epub 2022 May 27. PMID: 36395809.

TROG 12.01 HPV OROPHANYX

Rischin D, Mehanna H, Young RJ, Bressel M, Dunn J, Corry J, Soni P, Fulton-Lieuw T, Iqbal G, Kenny L, Porceddu S, Wratten C, Robinson M, Solomon BJ; Trans-Tasman Radiation Oncology Group and the De-ESCALaTE HPV Trial Group. Prognostic stratification of HPV-associated oropharyngeal cancer based on CD103+ immune cell abundance in patients treated on TROG 12.01 and De-ESCALaTE randomized trials. Ann Oncol. 2022 Aug;33(8):804-813. doi: 10.1016/j.annonc.2022.04.074. Epub 2022 May 4. PMID: 35525376.

TROG 07.01 DCIS

Chua BH, Link EK, Kunkler IH, Whelan TJ, Westenberg AH, Gruber G, Bryant G, Ahern V, Purohit K, Graham PH, Akra M, McArdle O, O'Brien P, Harvey JA, Kirkove C, Maduro JH, Campbell ID, Delaney GP, Martin JD, Vu TTT, Muanza TM, Neal A, Olivotto IA; BIG 3–07/TROG 07.01 trial investigators. Radiation doses and fractionation schedules in non-low-risk ductal carcinoma in situ in the breast (BIG 3-07/TROG 07.01): a randomised, factorial, multicentre, open-label, phase 3 study. Lancet. 2022 Aug 6;400(10350):431-440. doi: 10.1016/S0140-6736(22)01246-6. PMID: 35934006.

TROG 14.02 RAIDER

Webster A, McNair HA, Hansen VN, Lewis R, Patel E, Miles E, Hall E, Hafeez S, Huddart R; RAIDER, HYBRID Trial Management Groups. Recognising the challenges of implementing multi-centre adaptive plan of the day radiotherapy. Tech Innov Patient Support Radiat Oncol. 2022 Feb 9;21:31-35. doi: 10.1016/j.tipsro.2022.01.002. PMID: 35198744; PMCID: PMC8841376.

Collaborative studies & projects

(TROG 08.04) PORTEC – 3

Wortman BG, Post CCB, Powell ME, Khaw P, Fyles A, D'Amico R, Haie-Meder C, Jürgenliemk-Schulz IM, McCormack M, Do V, Katsaros D, Bessette P, Baron MH, Nout RA, Whitmarsh K, Mileshkin L, Lutgens LCHW, Kitchener HC, Brooks S, Nijman HW, Astreinidou E, Putter H, Creutzberg CL, de Boer SM. Radiation Therapy Techniques and Treatment-Related Toxicity in the PORTEC-3 Trial: Comparison of 3-Dimensional Conformal Radiation Therapy Versus Intensity-Modulated Radiation Therapy. Int J Radiat Oncol Biol Phys. 2022 Feb 1;112(2):390-399. doi: 10.1016/j.ijrobp.2021.09.042. Epub 2021 Oct 2. PMID: 34610387.

Khaw P, Do V, Lim K, Cunninghame J, Dixon J, Vassie J, Bailey M, Johnson C, Kahl K, Gordon C, Cook O, Foo K, Fyles A, Powell M, Haie-Meder C, D'Amico R, Bessette P, Mileshkin L, Creutzberg C L, Moore A. Radiotherapy Quality Assurance in the PORTEC-3 (TROG 08.04) Trial. Clin Oncol (R Coll Radiol). 2022 Mar;34(3):198-204. doi: 10.1016/j.clon.2021.11.015[MS6]. PMID: 34903431

SEAFARER

Lehmann J, Hussein M, Barry M, Siva S, Moore A, Chu M, Diez P, Eaton D J, Harwood J, Lonski P, Mackonis E C, Meehan C, Patel R, Ray X, Shaw M, Shepherd J, Smyth G, Standen T S, Subramanian B, Greer P B, Clark C H. A new concept for validating radiotherapy patient specific QA for clinical trials and clinical practice. Radiotherapy and Oncology. 2022 April; 171 (5). DOI:10.1016/j.radonc.2022.04.01. PMID: 35461949

Secondary Data Analysis

TROG 12.01 HPV OROPHANYX

McDowell L, Rischin PD, King M, Kenny L, Porceddu S, Wratten C, Macann A, Jackson JE, Bressel M, Fua T, Lin C, Liu C, Corry J. Patient- and clinician-reported outcomes in human papillomavirus-associated tonsillar carcinoma treated with unilateral and bilateral intensity-modulated radiotherapy - a substudy from TROG12.01. Int J Radiat Oncol Biol Phys. 2022 Aug 9:S0360-3016(22)03089-9. doi: 10.1016/j.ijrobp.2022.08.006. Epub ahead of print. PMID: 35961477.

Multitrial analysis including TROG 99.06 and TROG 03.01 RADAR

Kishan AU, Sun Y, Hartman H, Pisansky TM, Bolla M, Neven A, Steigler A, Denham JW, Feng FY, Zapatero A, Armstrong JG, Nabid A, Carrier N, Souhami L, Dunne MT, Efstathiou JA, Sandler HM, Guerrero A, Joseph D, Maingon P, de Reijke TM, Maldonado X, Ma TM, Romero T, Wang X, Rettig MB, Reiter RE, Zaorsky NG, Steinberg ML, Nickols NG, Jia AY, Garcia JA, Spratt DE; MARCAP Consortium group. Androgen deprivation therapy use and duration with definitive radiotherapy for localised prostate cancer: an individual patient data meta-analysis. Lancet Oncol. 2022 Feb;23(2):304-316. doi: 10.1016/S1470-2045(21)00705-1. Epub 2022 Jan 17. PMID: 35051385.

Multitrial analysis including TROG 99.06[MS13] [RM14] [MS15] and TROG 03.01 RADAR

Kishan AU, Steigler A, Denham JW, et al. Interplay Between Duration of Androgen Deprivation Therapy and External Beam Radiotherapy With or Without a Brachytherapy Boost for Optimal Treatment of High-risk Prostate Cancer: A Patient-Level Data Analysis of 3 Cohorts. JAMA Oncol. 2022;8(3):e216871. doi:10.1001/jamaoncol.2021.6871. PMID: 35050303/

TROG 08.03 RAVES

van Gysen K, Kneebone A, Le A, Wu K, Haworth A, Bromley R, Hruby G, O'Toole J, Booth J, Brown C, Pearse M, Sidhom M, Wiltshire K, Tang C, Eade T. Evaluating the utility of knowledge-based planning for clinical trials using the TROG 08.03 post prostatectomy radiation therapy planning data. Phys Imaging Radiat Oncol. 2022 May 13;22:91-97. doi: 10.1016/j.phro.2022.05.004. PMID: 35602546; PMCID: PMC9117914.

General

Chang D, Moore A, van Dyk S, Khaw P. Why Quality Assurance is Necessary in Gynecologic Radiation Oncology. Int J Gynecol Cancer. 2022 Mar;32(3):402-406. doi: 10.1136/ijgc-2021-002534. PMID:35256429/

Participating in our subspecialty working parties, Special Interest Groups and Committees, supports & advances radiation medicine research.

Multidisciplinary committees

- **provide peer review**
- **advise the TROG Scientific Committee (TSC)**

Trials & projects

Research gaps & priorities

New treatments & techniques

Scientific merit

new ideas

TROG CANCER RESEARCH

partnerships

collaborations

guidelines & policies

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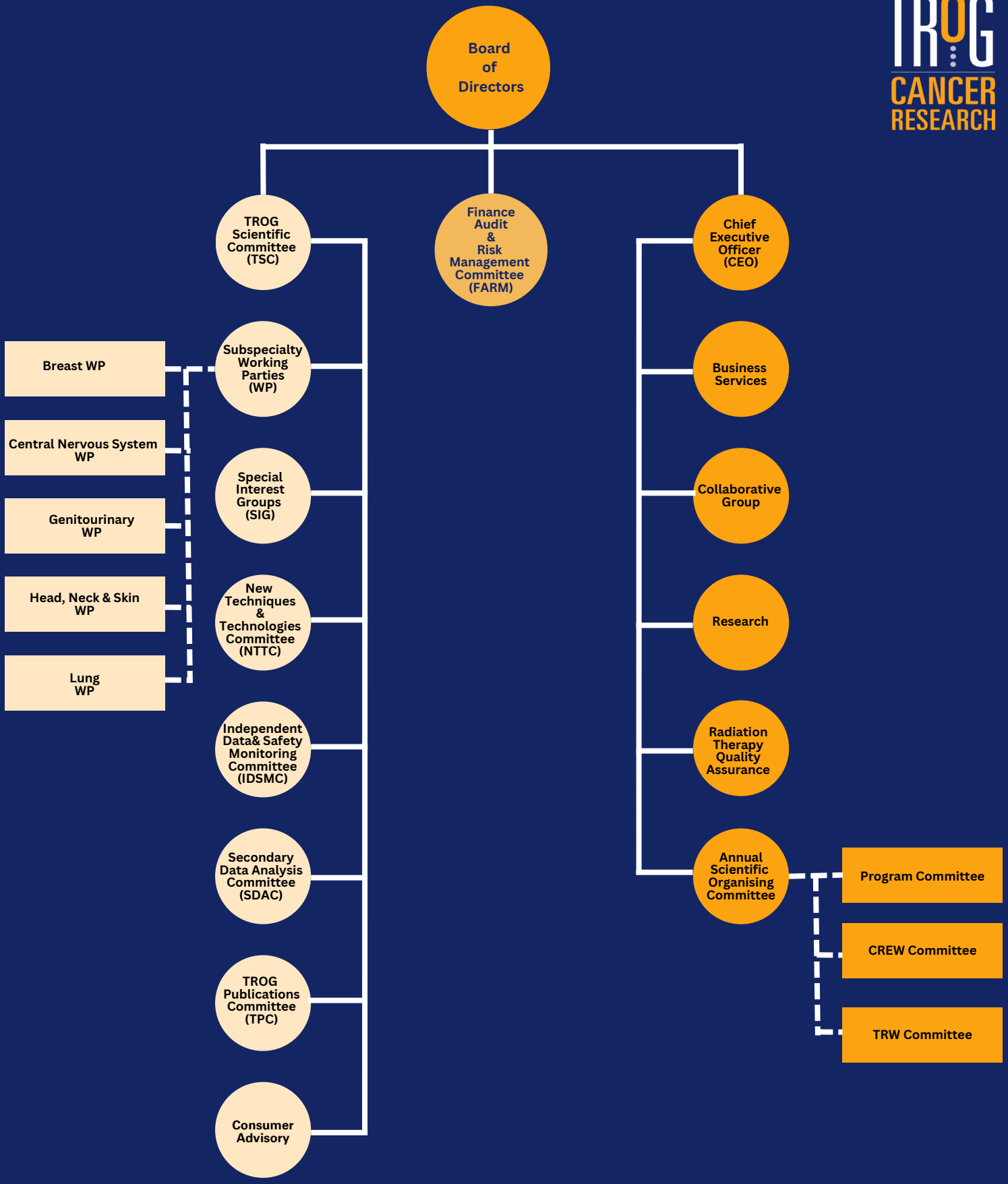
Improve outcomes for people affected by cancer



TROG Cancer Research Organisational Structure

our
Board of Directors

Professor Trevor Leong


President/ Chairperson
MBBS, MD, FRANZCR
Radiation Oncologist and past Director of Division of Radiation Oncology, Peter MacCallum Cancer Centre;
Director AGITG, Company Secretary AGITG.

Associate Professor Purnima Sundaresan
Full Member Director
MBBS, BSc (Hons), FRANZCR, PhD
Consultant Radiation Oncologist Blacktown and Westmead Hospitals.
Clinical academic The University of Sydney,
Associate Editor, Journal of Medical Imaging and Radiation Oncology
Chair Of Board of Head and Neck Cancer Australia.

Doctor Fiona Hegi-Johnson


Full Member Director
Chair, TROG Lung Working Party
Finance, Audit & Risk Management Committee
MBBS (Hons 1), BSc. Med (Hons)
Radiation Oncologist, Breast, Lung & SABR Service,
Peter MacCallum Cancer Centre.
Senior Research Fellow, University of Melbourne.

Professor Annette Haworth
Full Member Director
FACPSEM, PhD, MSc, BSc (Hons)
Professor of Medical Physics, University of Sydney
Director, Institute of Medical Physics.
Life Member of TROG with more than 20 years serving on multiple clinical trials and TROG committees.

Associate Professor Sashendra Senthi


Full Member Director
Scientific Committee Chairperson
BHB, MBChB, PhD, MPH, FRANZCR
Radiation Oncologist Alfred Health Melbourne
Associate Professor Monash University.

Doctor Melissa James

Full Member Director NZ
MBBS BSc (hons) FRANZCR (UNSW)
Radiation Oncologist, Canterbury District Health Board New Zealand
Senior Lecturer at Otago University

Doctor Tim Kuypers

Independent Director
Finance, Audit & Risk Management Committee Chairperson
GAICD, PhD Economics, ACCA Diploma in Accounting and Finance.
Special Advisor at Houston Kemp Economists.
Member of Metro Trains Melbourne Board Safety Committee
Standards Board Australia.
Experienced non-executive director and senior executive.
Significant expertise in highly regulated industries of transport and telecommunications.

Mrs. Susan Naeyaert

Independent Director
Finance, Audit & Risk Management Committee
BPharm, Grad Dip SC(Pharm) MCom
Over 20 years experience in pharmaceutical industry, in health economics, pricing and government policy. Experience in the US, Europe and Asia whilst having both Global and regional responsibilties.
European Organisation for Research and Treatment in Cancer (EORTC) use of Quality of Life instruments in randomised clinical trials.

Mr. Andrew Beck

Independent Director
(appointed April 2022)
Finance, Audit & Risk Management Committee
Experienced in-house lawyer and General Counsel at Pacific National.
Experienced Director
Enjoys working with people to improve processes and develop strategies to generate valuable outcomes.

Mr. Murray McLachlan

Independent Consumer Representative Director
(appointed April 2022)
Deputy Chair of Cancer Voices NSW
Health Consumer NSW Board member.
Volunteered with Cancer Council NSW
Professional experience in the NSW public sector -policy and advocacy.
Personal cancer experience as both a person diagnosed with prostate cancer (successful treatment 2009) and as a long term partner and carer of a person diagnosed with pancreatic cancer (passing in 2007).

our
Board

Dr. Keen Hun Tai

Royal Australian and New Zealand College of Radiologist (RANZCR) Representative
MBBS, FRANZCR, MAICD
Deputy Director of Radiation Oncology and Consultant Radiation Oncologist, Peter MacCallum Cancer Centre.

our
2022 Retiring Board members

Mr. Denis Byron

Independent Director
(resigned April 2022)
Finance, Audit & Risk Management Committee
BComm, CPA
Experienced non-executive director, CEO and senior executive.
Certified Public Accountant since 1979 awarded Fellow status in 2010

Mr. Robert Ferguson

Independent Consumer Representative Director
(resigned April 2022)
Finance, Audit & Risk Management Committee
BA (Psychology), M Counselling
Consumer Advocate, St Vincent's Hospital.
NSW Cancer Council Telephone Support Group Co Facilitator.
Chairman, Muscular Dystrophy Foundation Australia;
President, Muscular Dystrophy NSW.
Member, Macquarie University Cancer Research Consumer Advisory Group.
Cancer Council of Victoria Optimum Cancer Pathway Governance Committee.
Director, Colliers International.

Trial Management

TROG Cancer Research's Central Operations Office is equipped to provide full trial coordination centre activities from the time of trial concept through management of trials to the completion and publication of trial research outcomes and results in medical journals.

TROG works with radiation therapy treatment centres and researchers to provide comprehensive clinical trial coordination and oversight to ensure:

- Participant recruitment and data collection targets are being met,
- Participant safety is maintained through risk based study monitoring approach,
- Data is being collected, recorded and collated to aid meeting primary/final endpoints,
- Data integrity,
- Regulatory compliance, and
- Reporting timelines to regulatory agencies are met.

The Research Services team led by Renee Swanson, also provide administrative support to Trial Chairpersons and the Trial Management Committees, and oversight of research by TROG Working Parties, TROG Scientific Committee (TSC) and TROG Publication Committee for the trial duration.

Trial Development

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

The services provided by Research Development are

- Expert review of trial concepts and protocols via TROG sub-specialty working parties and special interst groups, Cancer Australia funded national technical services and TROG Scientific Committee.
- Clinical trial protocol and budget development
- Coordination of research funding applications,
- Database development services and advice,
- Access to and maintainence of a suite of essential trial document templates for ethics applications and trial implementation at sites.
- Promotion of collaboration between other Collaborative Cancer Trial Groups and international organisations.

Research Development Services also include the planning, coordination and conduct of Concept Research Development Workshops such as:

- Radiation Medicine specific concept development workshops
- Collaborative tumour specific concept development workshops.

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

Radiation Therapy Quality Assurance

In order for the results of a trial to be published and adopted into clinical practice, data must be accurate.

Radiation Therapy Quality Assurance (RTQA) team led by Alisha Moore, provides the framework for verifying data accuracy and protocol compliance. It also ensures that safety issues for participants on a trial are identified as soon as possible and rectified.

The TROG Cancer Research RTQA team actively supports clinical trial activities through:

- Development of robust risk-adapted radiation therapy quality assurance programs,
- Development & review of radiation therapy planning, delivery and quality assurance guidelines,
- Monitoring protocol compliance and radiation therapy plan quality feedback,
- Management and oversight of research data,
- Maximising collaborative efforts to ensure TROG maintains high standards and responds to changing national and international best practice, and
- Ongoing horizon scanning and forward planning.

RTQA also reviews international standards for credentialing of new techniques, and incorporates the use of technologically advanced dosimetric phantoms and software. In doing this, TROG ensures researchers have access to the best available resources for conducting their research.

RTQA ia also the facilitator of the New Techniques and Technologies Committee and Sub-committees with an important role in the development of guidelines and recommendations.

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).

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, and member engagement. These services support TROG staff, members and the TROG research portfolio.

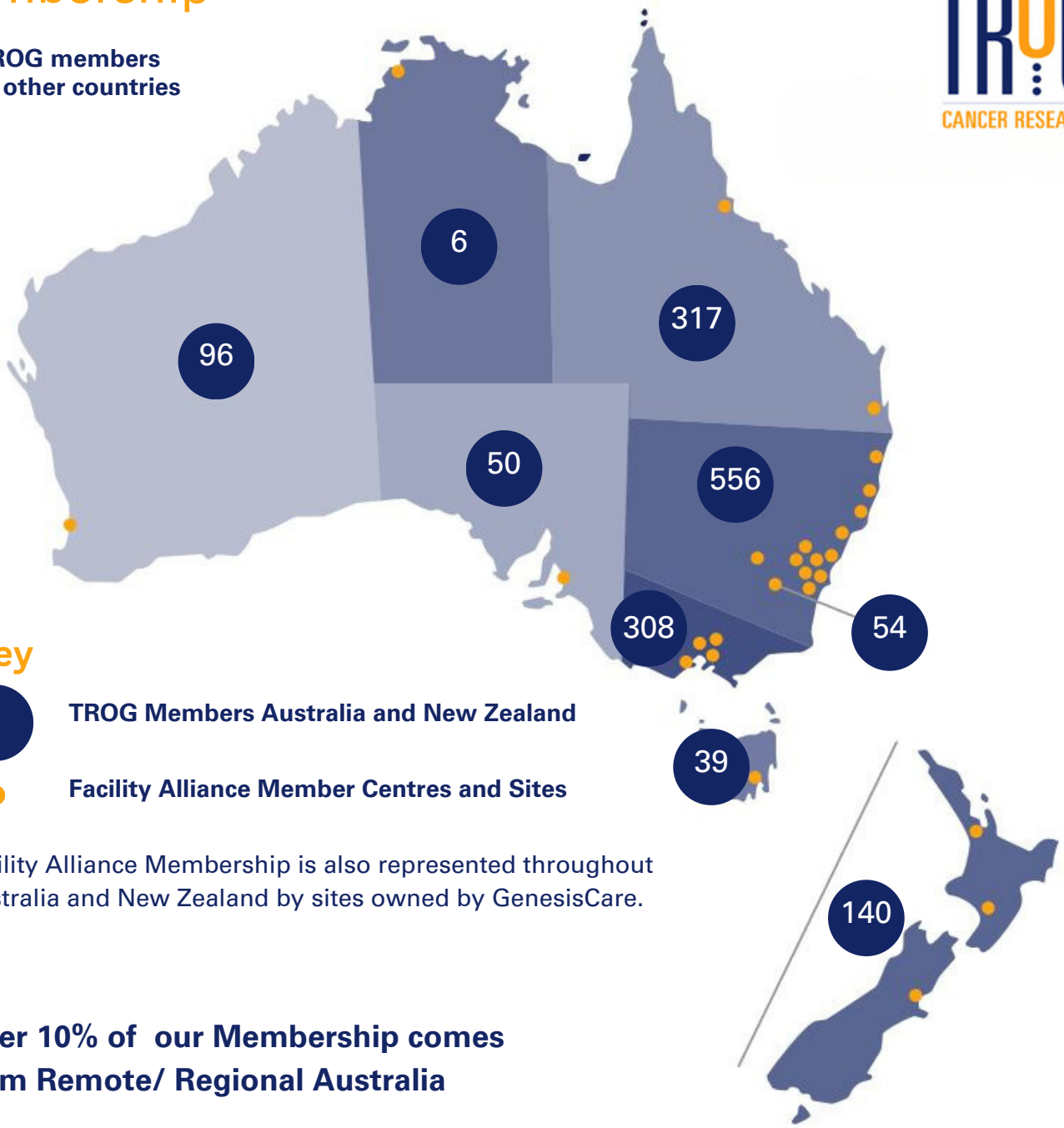
Business Services keep members informed of important events, fundraising activities, meetings and educational opportunities such as the Annual Scientific Meeting, Concept Development Workshops and special interest meetings and workshops.

The Business Services team keep the website up to date and coordinate member newsletters and social media posts. To fulfil these business functions in 2022 TROG has worked with a number of external businesses. These have included:

- Newton Green Technologies
- HR Assured
- Encanta Event Management
- The Marketing GP
- Cutcher & Neale Accounting & Financial Services

our membership

20 **TROG members in other countries**



Key

TROG Members Australia and New Zealand

Facility Alliance Member Centres and Sites

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

DISCIPLINE	2022	FULL LIFE MEMBER	AFFILIATE
Radiation Oncologists	360	160	200
Radiation Therapists	527	6	521
Radiation Oncology Registrars	132	3	129
Trial Coordinators/Data Managers	208	6	202
Medical Physicists	99	13	86
Medical Oncologists	7	2	5
Interventional Oncologists	9	1	8
Statisticians	6	0	6
Consumers/other	302	16	286
TOTAL MEMBERSHIP	1650	207	1443

become a

TROG Cancer Research member

Are you a medical professional with a strong interest in radiation medicine?
Can you see a future where all cancers can be targeted by one treatment?
Help us in our global effort to better control and cure cancer.

Become a TROG Cancer Research Member.

Join our network of over >1500 professionals in this exciting field.

Become a full TROG member

This membership is extended to anyone fully qualified in their discipline.

If you are a radiation oncologist, medical oncologist, radiation therapist, interventional oncologist, medical physicist, statistician, data manager, nurse, or surgeon, we welcome your input.

For just $180+gst per year, full TROG Cancer Research Members can:

- **Receive voting rights at meetings, on trial protocols and on other policies**
- **Become a Board Member or Trial Chair**
- **Submit proposals for new trials**
- **Receive support at all stages of a trial's development**
- **Strengthen grant applications by aligning with TROG Cancer Research**
- **Be assured that all trials are subject to and administered by our RTQA program.**

Become an Affiliate TROG member

Affiliate membership is FREE
It is also open to anyone qualified or training in a radiation therapy-related discipline and offers a range of benefits, including:

- **The opportunity to network with like-minded professionals**
- **Staying up to date with industry news and trial updates in our regular newsletters**
- **Access to trial resources and radiation therapy quality assurance resources**
- **Access to the knowledge of TROG Cancer Research specialised committees.**

All TROG Cancer Research members can access the member section of the website which includes:

- **Access to TROG e-learning platform encompassing GCP training and more.**
- **Copies of trial documents including protocols.**
- **Minutes and presentations from meetings.**
- **TROG Policy and Procedures Manuals.**
- **Access to trial and RTQA resources.**

Become a member today

our

Facility Alliance Membership (FAM)

The TROG Cancer Research Facility Alliance Membership continued to hold strong in 2022 after more than ten years since its inauguration in 2012. TROG is thrilled to be in collaboration with over 27 facilities throughout Australia and New Zealand, working together to improve patient outcomes via the implementation of clinical trials and new treatments.

The Facility Alliance Members enjoy the support of the TROG Central Operations Office by way of specialised IT support, expertise from sub specialty groups and partnership with Cancer Cooperative Trial Groups and expert services from our Radiation Therapy Quality Assurance team.

With the support of Hospital Radiation Oncology Departments and Cancer Treatment Centres involved in TROG trials and clinical research activities across Australia and New Zealand, the FAM allows us to continue our business as a Not For Profit organisation and achieve our mission of improving outcomes for people affected by cancer through research in radiation medicine.

Our Facility Alliance Members make a valuable contribution; supporting TROG to conduct investigator initiated scientifically robust clinical trials; allow 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.

We would like to wholeheartedly thank the facilities who support TROG and look forward to many more years of collaboration through this vital initiative.

A full list of 2022 FAM members can be found on our website and also **via this link.**

our

Research Highlights

Participant number milestone

TROG Cancer Research's 15,000th participant was recruited in May 2022. We thank all of the amazing participants, clinicians, radiation therapists, medical physicists, trial chairs, trial coordinators, statisticians and valued TROG members for their commitment over the last 30 years. This milestone highlights just how far TROG has come; with patients not only receiving the benefits of participating in clinical trials, but importantly, these participants have worked with TROG researchers to achieve research results that could potentially change lives for those affected by cancer through improved outcomes and life quality.

We could not be prouder of this milestone.

Member achievements

In November 2022, the AGITG Innovation Grant for Clinical Trials was awarded to Dr. Trang Pham for her research concept TD21.06 MR STAR (*Improved local control using adaptive MRR-guidance to target abdominal cancer with stereotactic ablative radiotherapy: A randomised phase II trial*). This trial, developed with TROGs MR in Radiation Therapy Special Interest Group, and approved for development by the TROG Scientific Committee 03 August 2022 will be conducted collaboratively between AGITG and TROG Cancer Research.

NHMRC Award for Prof. Trevor Leong

TROG President Prof. Trevor Leong was awarded the inaugural National Health and Medical Research (NHMRC) David Cooper Clinical Trials and Cohort Studies Award, announced at the NHMRC Research Excellence Awards ceremony held in Canberra on 31st March 2022.

The NHMRC David Cooper Clinical Trials and Cohort Studies Award is in remembrance of leading HIV/AIDS researcher Prof. David Cooper AC FAA FAHMS (1949-2018). NHMRC's Research Excellence Awards recognise individuals in health and medical research who are going above and beyond to treat and solve the health challenges that face our community.

Prof.Leong's work with TROG Cancer Research (TROG) and the Australasian Gastro-Intestinal Trials Group (AGITG) on the (AGITG AG0407GR/TROG 08.08) TOPGEAR Phase III trial (*Investigating the use of preoperative chemoradiotherapy versus preoperative chemotherapy for respectable gastric cancer*), which opened to patients in 2013, was noted by NHMRC as an important research question worthy of government funding.

Professor Leong is in it for the long run and hopes to continue working with TROG in the development of radiation medicine clinical trials and to improve cancer outcomes for many years. "All of us at TROG 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," Trevor said. "This award is only the beginning of more work to come and that's very exciting," he concluded.

Research Highlights: **TROG trial spotlight**

TROG 07.01 DCIS

Findings from Prof. Boon Chua's led **TROG 07.01 DCIS/BIG 3-07** Trial (Radiation doses and fractionation schedules in non-low-risk ductal carcinoma in situ in the breast (*BIG 3–07/TROG 07.01): a randomised, factorial, multicentre, open-label, phase 3 study*) have been recognised on a global scale in leading medical journal, The Lancet.

After 15 years of collaborating with researchers at 136 participating centres across six clinical trial organisations in 11 countries, Prof. Chua is grateful for the opportunity *The Lancet* provided to share the study results with a global research and health community to improve outcomes of women diagnosed with ductal carcinoma in situ (DCIS) of the breast. "DCIS is generally considered a form of non-invasive breast cancer, some of which could progress to become invasive cancer. It is a growing health issue since mammographic screening is widely available in many countries; today, it accounts for up to 25 per cent of new breast cancer diagnoses. However, in contrast to invasive breast cancer, there has been comparatively little research on DCIS. As a result, there are often uncertainties on how individual patients with DCIS may best be managed, especially to reduce the risk of their DCIS from becoming an invasive breast cancer."

This research study focuses on improving treatments for women diagnosed with DCIS.

Radiation treatment of the whole breast after surgery for DCIS decreases the chances of developing further cancer in that breast. In the **TROG 07.01 DCIS/BIG 3-07** trial, the researchers tested whether additional doses of radiation, called a boost, given specifically to the part of the breast that had the DCIS within it improves the chances of not having the cancer come back in the breast. The researchers also tested the best number of radiation treatments to treat DCIS.

A quick snapshot of these **findings** are as follows:

- Between June 25, 2007, and June 30, 2014, 1,608 patients were randomly assigned to have no boost (805 patients) or additional boost radiation (803 patients) after radiation treatment of the whole breast.
- 831 patients received 25 radiation treatments of the whole breast, and 777 patients received 16 radiation treatments of the whole breast.
- The 5-year free-from-local-recurrence rates were 92·7% (95% CI 90·6–94·4%) in the no-boost group and 97·1% (95·6–98·1%) in the boost group (hazard ratio 0·47; 0·31–0·72; p<0·001).
- The boost group had higher rates of grade 2 or higher breast pain (10% [8–12%] vs 14% [12–17%], p=0·003) and duration (6% [5–8%] vs 14% [11–16%], p<0·001).
- In patients with resected non-low-risk DCIS, a boost after whole breast irradiation reduced local recurrence with an increase in grade 2 or greater toxicity.
- There were no statistically significant differences in 5-year free-from-local-recurrence rates between patients who had 25 radiation treatments of the whole breast (94·4%) and patients who had 16 radiation treatments of the whole breast (93·7%).

  The results provide the first randomised trial data to support the use of boost radiation after postoperative whole breast irradiation, and the shorter course (16 treatments) of whole breast irradiation in patients with non-low-risk DCIS to improve the balance of cancer control, treatment toxicity, and socio-economic burdens of treatment. The international scale of the study supports the generalisability of the results.

This global study led by TROG is possible thanks to our collaboration with the Breast International Group's (BIG) network of breast cancer research groups, which have been instrumental in the successful conduct of this high-quality trial. This trial was supported by funding from the Australian National Health and Medical Research Council, Susan G. Komen for the Cure®, Breast Cancer Now, OncoSuisse Swiss Federation Against Cancer, Dutch Cancer Society and Canadian Cancer Society.

Research Highlight: **TROG trial Award**

TROG 18.06 FIG

(Prospective, multicentre trial evaluating FET-PET In Glioblastoma)

Congratulations to Assoc Prof. Eng-Siew Koh, Prof. Andrew Scott and the TROG 18.06 FIG Study team for being awarded the Chris Atkinson Award (Best Scientific Paper Presentation in Radiation Oncology) and the Elekta Award Advances in the Use of Technology in Radiation Therapy (Best Scientific Paper) at the 2022 RANZCR ASM. "This represents a tremendous team effort and so it's wonderful to receive this peer acknowledgement in recognition of the substantive work in relation to the FIG trial credentialling programme", said Assoc Prof. Koh, who gave particular thanks to Nathaniel Barry, PhD candidate at UWA for providing further Radiation Oncology and Nuclear Medicine analysis data.

Research Highlight: **new TROG trial**

TROG 21.07 SOCRATES HCC

(A randomised controlled trial of Standard Of Care versus RadioAblaTion in Early Stage HCC.)

Hepatocellular carcinoma (HCC) has one of the fastest rising incidence and mortality rate of any cancer, however, treatment options remain limited and 5-year survival is poor. Unlike most other cancers, the majority of people presenting with early-stage HCC are unable to receive curative intent local therapies or may progress following initial treatment with thermal ablation or transarterial therapies. Emerging data supports a role for stereotactic ablative body radiotherapy (SABR) as a well-tolerated, non-invasive treatment with high rates of local control with some centres now considering it a new standard of care.
However, randomised evidence comparing the various treatment options in the first line setting is lacking and many guidelines do not currently endorse its use leading to highly variable utilisation around Australia and internationally. Led by Prof. Alan Wigg and Assoc Prof. David Pryor and supported by Australasian Gastro-Intestinal Trials Group (AGITG), GESA and ARGANZ, SOCRATES HCC will compare SABR to other current first line treatments (thermal ablation, transarterial therapies) for non-surgical candidates with solitary (≤5cm) early-stage HCC, addressing this evidence gap.

Assoc Prof. David Pryor

Prof. Alan Wigg

Awarded MRFF Rare Cancers, Rare Diseases and Unmet Need funding in January 2022 and opened for recruitment in October, SOCRATES HCC aims to set a new benchmark in the management of HCC, improving access to effective curative intent therapies and enhancing inter-disciplinary collaboration.

Research Highlight: **TROG trial results**

TROG 13.01 SAFRON II

(Cost-Effectiveness of Single- versus Multi-Fraction SABR for Pulmonary Oligometastases)

The International Journal of Radiation Oncology - Biology - Physics (IJROBP) has highlighted **TROG 13.01 SAFRON II** in its December 2022 Podcast: Oligometastasis - The Special Issue. Editor-in-Chief Dr. Sue Yom hosted Assoc Prof. Shankar Siva, Trial Chair to discuss the May 2022 article "Cost-Effectiveness of Single- versus Multi-Fraction SABR for Pulmonary Oligometastases - The SAFRON II Trial".

Click here for the podcast

Trans Tasman Radiation Oncology Group (TROG) 13.01 **Randomized Phase II Trial**

Stereotactic Ablative Fractionated radiotherapy versus Radiosurgery for Oligometastatic Neoplasia to the lung (SAFRON II)

What is the optimal radiation approach for oligometastatic disease?

There is currently no evidence to guide an optimal approach for Stereotactic Ablative Body Radiotherapy (SABR) in patients with pulmonary oligometastases.

90 **patients** recruited between 2015 and 2018

13 **sites** across Australia and New Zealand

1 to 3 metastases of less than 5 cm that originated from a non-hematological malignancy

133 **metastases** treated

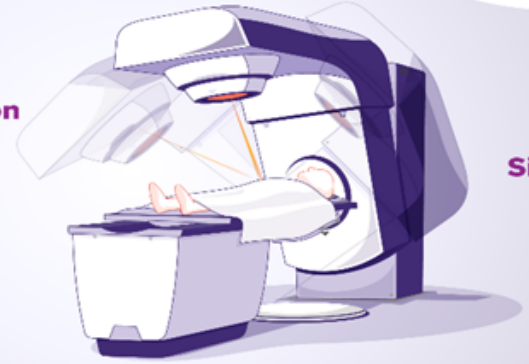
Randomization

balanced by number of metastases and tumour histology

Median follow-up: 3 years

Multiple Fraction (MF) SABR

4 x 12Gy
over 2 weeks
Total of 48 Gy



Single Fraction (SF) SABR

1 x 28Gy

Primary endpoint

SAFETY

Adverse Events Grade >3

MF	5%
SF	3%

No significant differences were found between SF and MF SABR.

Secondary endpoints

EFFICACY

(2 years)	Overall Survival	Local Control
MF	85%	83%
SF	88%	73%

	Median Disease Free Survival	Mean Time to Start of Systemic Therapy
MF	13.2 months	29.1 months
SF	14.3 months	28.9 months

Quality of Life - Patient reported outcomes
No detriment observed throughout assessment period

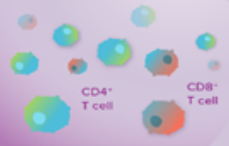
No significant difference was found between SF and MF SABR for any efficacy outcome. Both are safe, effective and do not impact quality of life.

Translational outcomes

Peripheral blood was collected in subset of 18 participants

- Plasma (CBA)
- PBMCs (CyTOF)
- PBMCs (FACS)

T Cell proliferation



% CTLA-4 and PD-1 expressing CD4 and CD8 T cell significantly increased

Both SF and MF SABR induced systemic immune activation.

Resource use

Per patient costs of SABR care
(incl. planning, simulation, delivery, HCP and patient time)

MF	AUD $4,827
SF	AUD $3,706

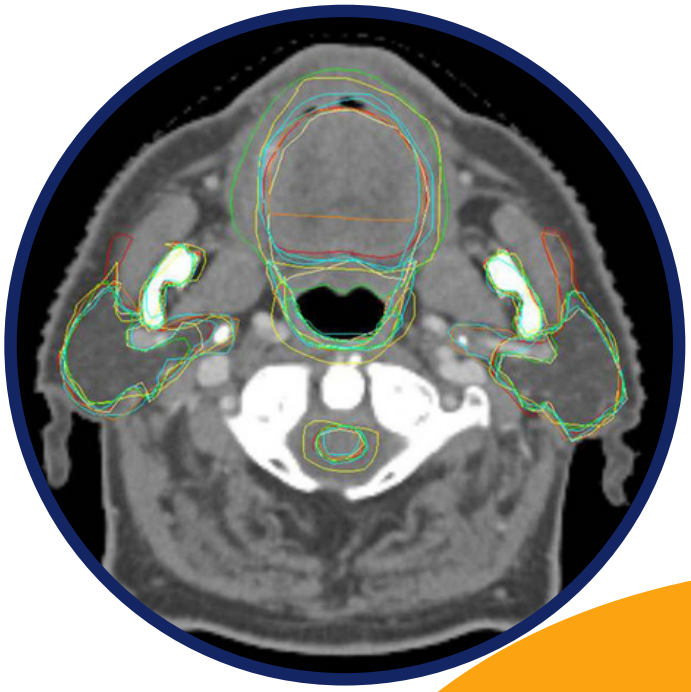
Shorter duration SF SABR may be preferred from a resource and patient's perspective.

Australian Government Cancer Australia · Peter Mac · Cancer Council Victoria · ALTG · varian A Siemens Healthineers Company · TROG CANCER RESEARCH

Design by oncodesign.com

Research Highlights: **TROG engagement**

TROG Plan and Contour Accuracy Challenges



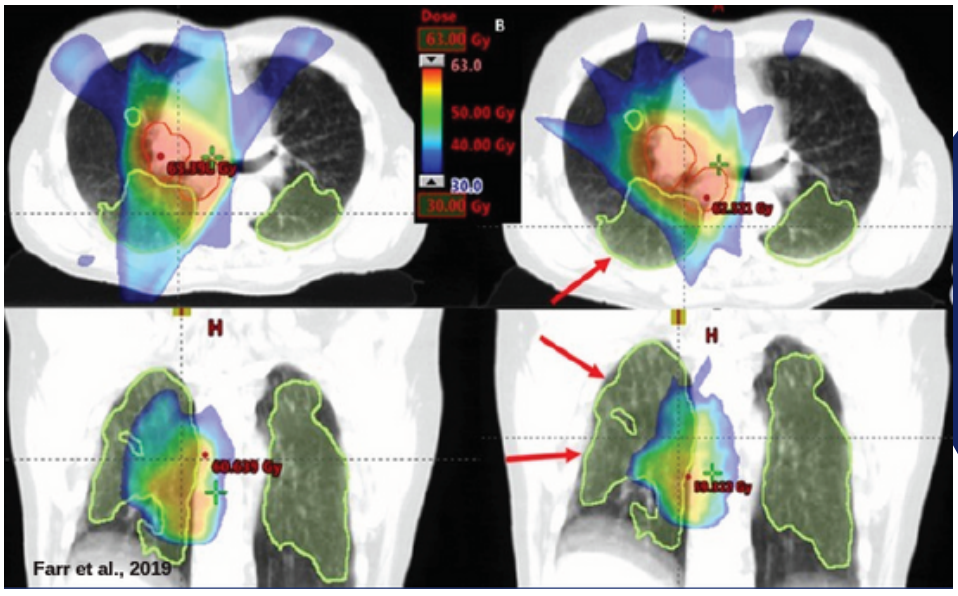
In 2022, TROG Cancer Research and Elekta collaborated on the TROG Plan Challenge and Contour Accuracy Studies. We were delighted to see the national and international radiation oncology community come together to participate.

The TROG Plan Challenge was run in preparation for Professor Paul Keall's collaborative new clinical trial, Ventilation Imaging for Thoracic Lung cancer radiation therapy (VITaL). This was a fantastic opportunity for participants to challenge their skills, in a relatively novel field of research. The goal of the plan challenge was to reduce dose to functional lung, while meeting target and anatomical organ at risk (OAR) dose objectives.

The contouring challenge focused on head and neck cancer OAR and allowed for three categories of participation: Category 1: a set of 'gold standard' OAR consensus contours generated by multiple expert H&N Radiation Oncologists; Category 2: a set of contours generated from multiple auto-segmentation platforms; Category 3: a set of contours generated by the radiation oncology community (human observers).

The results of the 2022 TROG Plan Challenge and Contouring Accuracy Studies were presented at the TROG Technical Research Workshop, as part of the TROG Annual Scientific Meeting on the Gold Coast (Australia) in June 2022.

We saw widespread engagement and applauded the high calibre of submissions. We look forward to more collaborative challenges in the future.



Research Highlights: **Key Projects**

SEAFARER

(Sensitivity assessment system to improve quality in Radiation Oncology treatments)
Principal Investigator: Prof. Peter Greer

The quality of radiation therapy delivery has been shown to significantly impact clinical outcomes including patient survival. To identify errors, institutions perform Patient Specific Quality Assurance (PSQA) assessing each individual radiation therapy plan prior to starting patient treatments. Externally administered Dosimetry Audits have found problems despite institutions passing their own PSQA. Hence a new audit concept which assesses the institution's ability to detect errors with their routine PSQA has been developed. The Sensitivity assessment system to improve quality in Radiation Oncology treatments (SEAFARER) will address this gap.

SEAFARER assesses the sensitivity and accuracy of a sites own internal quality assurance processes to detect known errors/discrepancies. SEAFARER was awarded funding through Cancer Australia via the priority-driven Collaborative Cancer Research Scheme (2022).

VESPA

(Virtual EPID Standard Phantom Audit)
Principal Investigator: Prof. Peter Greer

In 2022, VESPA continued to help facilitate 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.

TROG greatly appreciates the continued efforts and support of Prof. Peter Greer in the provision of this service.

Research Highlights: **trial participant focus**

Mr. Phillip Bambach

The journey to becoming the 200th participant for the TROG 18.01 NINJA Radiation Therapy Trial has been a remarkably quick process for Raymond Terrace resident, Phillip Bambach. Phillip was diagnosed with prostate cancer after he visited his GP for a flu shot. With recent years of the pandemic, he thought it wise to keep up to date with regular GP check-ups. A routine blood test by a nurse revealed an elevated prostate-specific antigen (PSA) level. This prompted his GP to send Phillip for further tests.

"I remember the process being incredibly fast. I was obviously overwhelmed with my diagnosis of prostate cancer and then being referred to different specialists, was something that I had never experienced before," Phillip said. "I was asked to return for more blood tests, and an MRI. Then before I knew it, I was listening to my doctor tell me I had prostate cancer."

Testing conducted by his urologist revealed Phillip had three tumours in his prostate, with no symptoms or indications prior to his diagnosis. This understandably came as a great shock. "I was overwhelmed by the news but looking back I think I was more focused on moving forward with treatment. I just didn't want to be in pain or cause any stress for my family.".

Since his diagnosis, Phillip has been able to balance his time between family and treatment, thanks to the NINJA Trial. The NINJA Trial compares the effectiveness of two schedules of radiation therapy for the treatment of patients with prostate cancer. It requires potential participants who have not been diagnosed with a prior or secondary type of cancer. And the cancer can't have spread to other parts of the body. For Phillip, the NINJA Trial opportunity was introduced to him swiftly after his diagnosis. "My Urologist sent me to Prof. Jarad Martin for a second opinion and he then suggested I participate in the research trial." "I was in overall general good health, and Prof. Martin answered every question I had and he didn't overwhelm me with information, so I had no hesitation saying yes."

Radiation Oncologist at Genesis Care and Co-Lead Investigator for the NINJA Trial, Prof. Jarad Martin said that providing greater access to treatment for cancer patients is an important step for the future of cancer treatment. "Clinical trials are how we lift our game in cancer care and are a mission-critical component of modern oncology," Prof. Martin said. "It is fantastic that participants in regional communities, such as Maitland have access to leading edge clinical trials, right on their doorstep."

Phillip was impressed by the new technology and how friendly and supportive the team of nurses and doctors were, during the trial. "I had no knowledge of radiation therapy before my treatment. I had no experience with cancer, so having my doctors and nurses answer any questions I had, made me and my wife feel reassured," Phillip recalled.

The NINJA Trial is focused on leveraging state of the art radiation technology and advanced imaging to test the effectiveness of fewer treatments for localised prostate cancer patients. Participants in the NINJA Trial can expect one of two shorter schedules of radiation therapy while traditional radiation treatment can require up to seven weeks of daily treatments. For Phillip, this meant a decrease to five treatments over two weeks. Phillip's experience has been a vital part of raising awareness of TROG Cancer Research's NINJA Trial and marks an important milestone in the clinical trial.

Phillip said the TROG Cancer Research team were great to work with throughout the trial.

"If I had a question, they were ready to answer it, the amount of information available about the treatment experience really took the worry off my shoulders. I also felt like I was doing something great for the community."

The light at the end of the tunnel Phillip's radiation therapy treatments at GenesisCare Maitland concluded on Friday 9 September 2022, and he has been vocal about how efficient and informative the process has been. "The option to take the treatments, only twenty minutes from my house made the process incredibly easy." Phillip concluded that the minimal side effects and option to pause treatment at any moment were a great reason to contribute to the clinical trial. "The shorter trial treatment times were a big factor in why I decided to participate in this trial. I wanted to spend time with my family and grandkids and not be stuck in hospital.
"I also wanted to give this trial the best chance to succeed, if I could help future generations who suffer with cancer that would be a great outcome from this experience."

TROG *annual scientific meeting*

Celebrating and bringing radiation medicine research to the forefront at our 2022 ASM

After a hiatus from in-person events due to COVID-19 restrictions, it was great to come together for our in-person 2022 Annual Scientific Meeting on the Gold Coast.

Hosted at the RACV Royal Pines Resort from 30 June to 3 July, our theme was **'Emerging and Evolving'** and the line-up of industry-leading speakers and workshops matched the brief.

We would like to sincerely thank Co-Convenors, Assoc Prof. Sid Baxi, Ms. Hayley Brennan and Mr. David Willis for their commitment to bringing life and laughter to our TROG 2022 ASM.

This was also made possible by the organisation and event coordination provided by the team at Encanta Event Management. This was the first time their team hosted the event in-person, and it was great to see all their groundwork come to fruition.

In addition, we recognise the hard work of our Organising and Program Committees, who helped to orchestrate a seamless ASM event featuring insights from leaders in radiation medicine.

Across the four-day event, we were honoured to hear from over 80 speakers from Australia, New Zealand and further abroad about the ever-evolving landscape of cancer research and radiation medicine, clinical trial developments, quality assurance techniques, advancements in technology, and so much more.

Among the list of speakers, we got to hear from Dr. Wally Curran (USA), Dr. Michelle Wilson (Auckland), Prof. Dorothy Keefe (Australia), Dr. Amar Kishan (USA), Assoc Prof. Kate Burbury (Australia), Dr. Madhavi Chilkuri (Australia) + more!

We are very appreciative of all our speakers who joined our event, virtually or in-person, from all corners of the world to share their work and developments in radiation medicine.

In addition to our workshops and plenary sessions, we had vast opportunities to network and connect with colleagues and other industry professionals while learning more about the work of our exhibitors and sponsors.

Our 2022 Exhibitors & Sponsors
If it weren't for our generous exhibitors and sponsors, we wouldn't have been able to host another ASM of this magnitude. We thank you for your commitment and support and hope that you come on board again to support us in 2023.

Our Gala Dinner, 'Gold on the Gold Coast'.
At our 'Gold on the Gold Coast' themed Gala Dinner, we were able to recognise the achievements of our team and cancer research community including TROGs central team members, collaborating members, hospitals, research centres and partners for all their hard work and commitment to cancer research. We also announced the great achievement of 15,000 trial participants over 30 years of TROG. This was met with great excitement and set the tone for a fabulous night of fun and frivolity.

Thank you to our participants!
Lastly, but certainly not least, we are so appreciative of all the over 270 participants who came together at our 2022 ASM. We hope you all enjoyed coming back together for our in-person event and gained a lot of valuable insight from our range of speakers and hosted workshops.

More highlights can be found here

Annual Scientific Meeting (ASM) 2022 Committee

Organising and Program Committee

Assoc Prof. Sid Baxi, (Convenor), Radiation Oncologist
Ms. Hayley Brennan, (Convenor), Radiation Therapist
Mr. David Willis, (Convenor), Radiation Therapist
Ms. Susan Goode, TROG Chief Executive Officer
Ms. Rebecca Montgomery, TROG Research Development Lead
Ms. Alisha Moore, TROG Radiation Therapy Manager, TRW
Ms. Narelle Williams, TROG Research Services Manager, CREW
Ms. Renee Swanson, (TROG Program Committee Representative), TROG Research Services Manager, CREW
Prof. Tomas Kron, Medical Physicist, TRW
Dr. Lachlan McDowell, Radiation Oncologist
Dr. Wee Loon Ong, Radiation Oncologist
Dr. Yu Yang Soon, Radiation Oncologist

Clinical Research Education Workshop Committee

Ms. Adrienne See, Cancer Trials Unit Manager, CREW
Ms. Amanda Woods, Radiation Oncology Research Lead, CREW
Ms. Debra Morris, Clinical Trials Coordinator, CREW
Ms. Xiaolu Wang, Clinical Trials Coordinator, CREW
Ms. Sue McCullough, Consumer, CREW
Ms. Trish Jenkins, Clinical Trial & Ethics Submission Coordinator, CREW
Ms. Kathryn Jajko, Research Lead – Radiation Oncology, CREW
Ms. Jackie Buck, TROG Clinical Research Associate, CREW

Technical Research Workshop Committee

Prof. Joerg Lehmann, Medical Physicist, Co-Chair TRW
Ms. Laurel Schmidt, Radiation Therapist, Co-Chair TRW
Ms. Olivia Cook, TROG Quality Assurance Radiation Therapist, TRW
Assoc Prof. Nick Hardcastle, Medical Physicist, TRW
Mr. Dean Wilkinson, Medical Physicist, TRW
Mr. Rob McDowall, Radiation Therapist, TRW
Prof. Paul Keall, Medical Physicist, TRW
Dr. Hilary Byrne, Medical Physicist, TRW
Dr. John Kipritidis, Medical Physicist, TRW
Mr. Mahesh Chandroth, Medical Physicist, TRW
Ms. Narelle Wallace, Radiation Therapist, TRW
Mr. Johnson Yuen, Medical Physicist, TRW
Ms. Peta Lonski, Medical Physicist, TRW
Mr. Fahim Siddiqi, Radiation Therapist, TRW
Ms. Rachael Dykyj, TROG Quality Assurance Research Officer, TRW
Ms. Alana Rossi, TROG Quality Assurance Radiation Therapist, TRW

TROG CANCER RESEARCH

AUSTRALIA AND NEW ZEALAND'S LEADING CONFERENCE FOR RADIATION MEDICINE RESEARCH

2023 TROG ANNUAL SCIENTIFIC MEETING

Accelerating Forward

19 - 22 June 2023

Hilton Adelaide, South Australia

MEET THE SPEAKERS

TROG 2023 ANNUAL SCIENTIFIC MEETING

ADAM HOLTZMAN
International Keynote

JUSTIN BAKER
International - Virtual

RYOHEI SASAKI
International

MELANIE LOVELL
National - Virtual

CATHERINE OSBORNE
National

MARTIN EBERT
National

TROG Cancer Research

annual scientific meeting 2024

Newcastle City
March 2024

Learning, sharing & building a stronger TROG

Bringing it Home

our

Consumer engagement

Mr. Murray McLachlan
Independent Consumer Representative Board Director

Having joined the TROG Cancer Research Board as its independent consumer representative in early 2022, I'm now more familiar with TROG's purpose and operation. Radiation oncology clinical trials provide an important opportunity not only to advance our understanding of what works in cancer radiation treatment, but also, and just as importantly, are the reason that many people are able to receive treatment that can be the difference between recovering and living well following a cancer diagnosis and the possibility that their illness may be life-limiting if not life-ending.

For that reason alone, the continuation of meaningful involvement of health consumers in clinical trials is of utmost importance. This must be more than involvement as a trial participant. Clinical trials can only be improved through the involvement of consumers who have direct experience of cancer either as a patient or as a family member or carer, as part of a research team from the very early stages so that they can help shape the purpose of the trial.

In joining the TROG Board, I felt that my experience in cancer advocacy and as a research consumer, developed over eight years, particularly through Cancer Voices Australia and Cancer Voices NSW and as a board member of Health Consumers NSW, would continue and enhance the consumer perspective at the board level.

Just as importantly, I see my role on the board as extending beyond representing the voice of consumers. I am interested in, and aware of, the bigger picture of the operation of TROG Cancer Research including in terms of its strategic direction and financial viability. The interests of people undergoing radiation therapy for cancer are best served by an organisation that functions well and that continues to produce outcomes that directly benefit those affected by cancer.

Mrs Susan McCullough OAM
Lung Cancer Representative and Advocate.

I have been a 'consumer member', of TROG Cancer Research since Rebecca Montgomery, helped run a consumer training session I attended, a lot of years ago, well before the Hobart ASM, that I was invited to attend. I have been a member of the TROG CREW Committee since just after that. It has given me the insight into how the people behind running clinical trials work, and all the behind the scenes work that make radiation trials run successfully.

I have been asked to speak at the upcoming IASLC WCLC 2023, as a research patient advocate, on a patients perspective of curable early stage Lung Cancer and treatment options available, it is also with opportunities like that, consumers can promote the importance of continuing research into improving patient outcomes with the different types of radiation treatment available.

I have attended all the TROG ASM's since then even via zoom during COVID, and have found TROG to be an excellent supporter of consumer input into Clinical Trials.

our

Fundraising and Events

Myall Lakes Veteran's annual TROG Golf Day

Held on Friday 4th November in lovely weather, golfers gathered once again for the Myall Lakes Veteran's annual TROG Cancer Research fundraiser at Hawks Nest Golf Club. TROG thanks the Hawks Nest Golf Club for their unwavering support year on year with this year showing no exception to the generosity displayed by the group. Efforts this year raised an amazing $1,800, up on last year's donation by several hundred dollars, the strength of support just keeps growing. Ms. Alisha Moore, TROG Radiation Therapy Manager, attended on the day and spoke to the attendees, who appreciated that TROG research can benefit all people touched by cancer. This included some of the golf club members themselves. A huge thanks to the Myall Lakes Veterans and Hawks Nest Golf Club.

Coffee collaboration

TROG Cancer Research, Marketing GP and Peaberrys coffee roasters, created a signature coffee blend for a good cause.

The NewyWay Blend

Carefully selected and roasted to represent the community they share, a percentage of proceeds from every purchase of coffee beans supported TROG Cancer Research to help improve outcomes and the quality of life of cancer patients for generations.

ASM Fundraising

Coordinated with the assistance of our marketing team, a series of fundraising activities were run throughout the ASM. This was a first for our ASM and the activities included a Mystery Wine Fundraiser and 100 Club Raffle.

We are delighted to announce that these fundraisers raised $3100 for TROG Cancer Research. Our team is beyond appreciative to those who got involved and we look forward to running more of these activities in the future

1st to 3rd December 2023

TREK for TROG

HELP TROG CANCER RESEARCH FIGHT CANCER

Hike To the Summit

In 2023, we will be hosting the Trek4TROG Kosi Challenge. This will be an amazing opportunity to climb the highest point in Australia, **Mt Kosciuszko** while helping to fundraise for **TROG Cancer Research**.

Trek4TROG is a unique opportunity to showcase your support alongside a team of trekkers. The team we are looking for will consist of 50 people, with a target of raising $25,000.

Join our Trek

This climb for a cause is a collaboration with the **Huma Charity Challenge**, who have been coordinating high-quality expeditions since the early 90s.

Throughout this fundraising trek you will get to experience three days of exploration, viewing Australia's natural landscapes and awe-inspiring scenes. Plus, you can bring your family or friends and build connections along the way.

Sponsor a Hiker or a team

If you are curious to learn more about the challenge or have any questions, we are here to help.

Talk to our team if you're interested in **joining us** or helping to **raise funds**.

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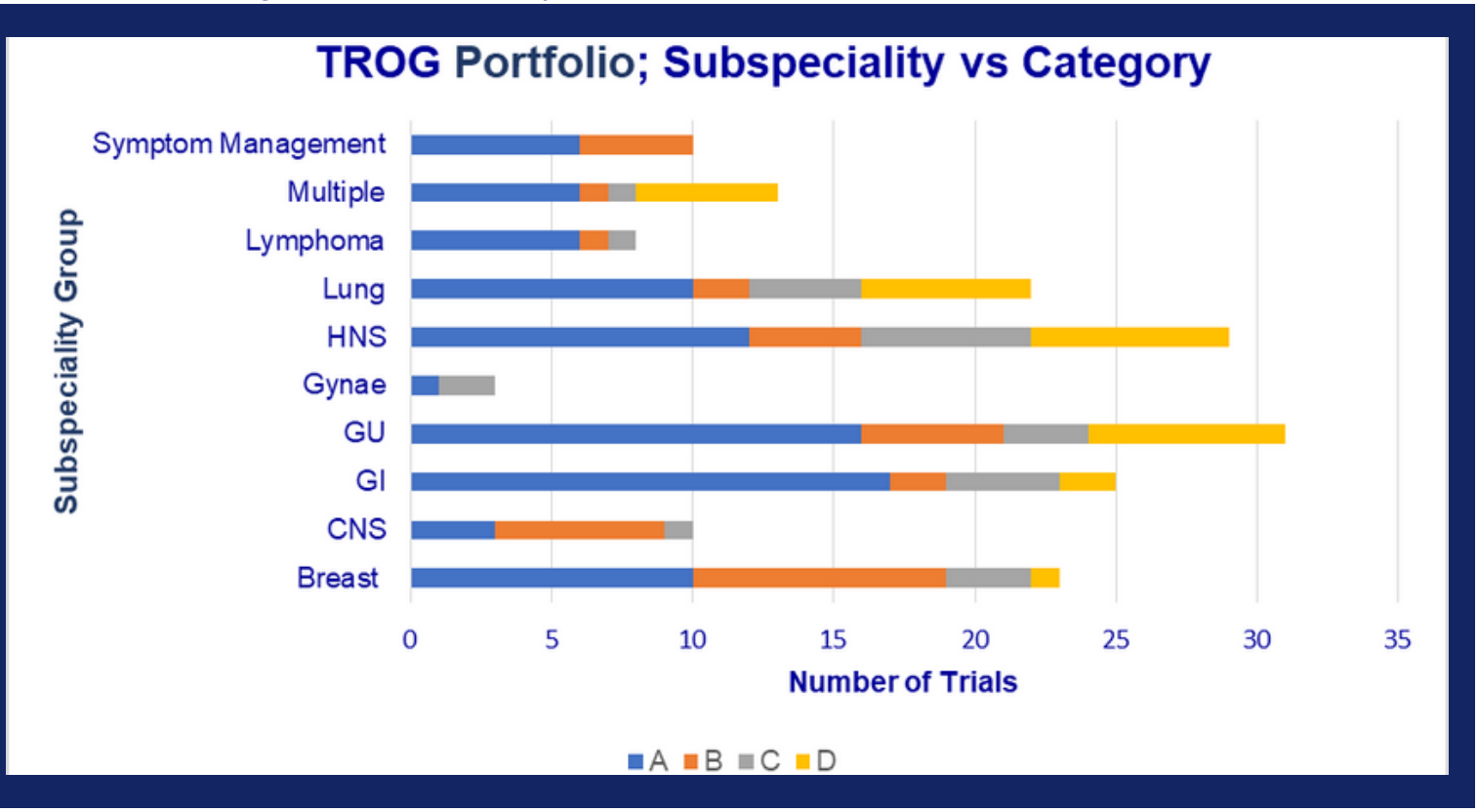
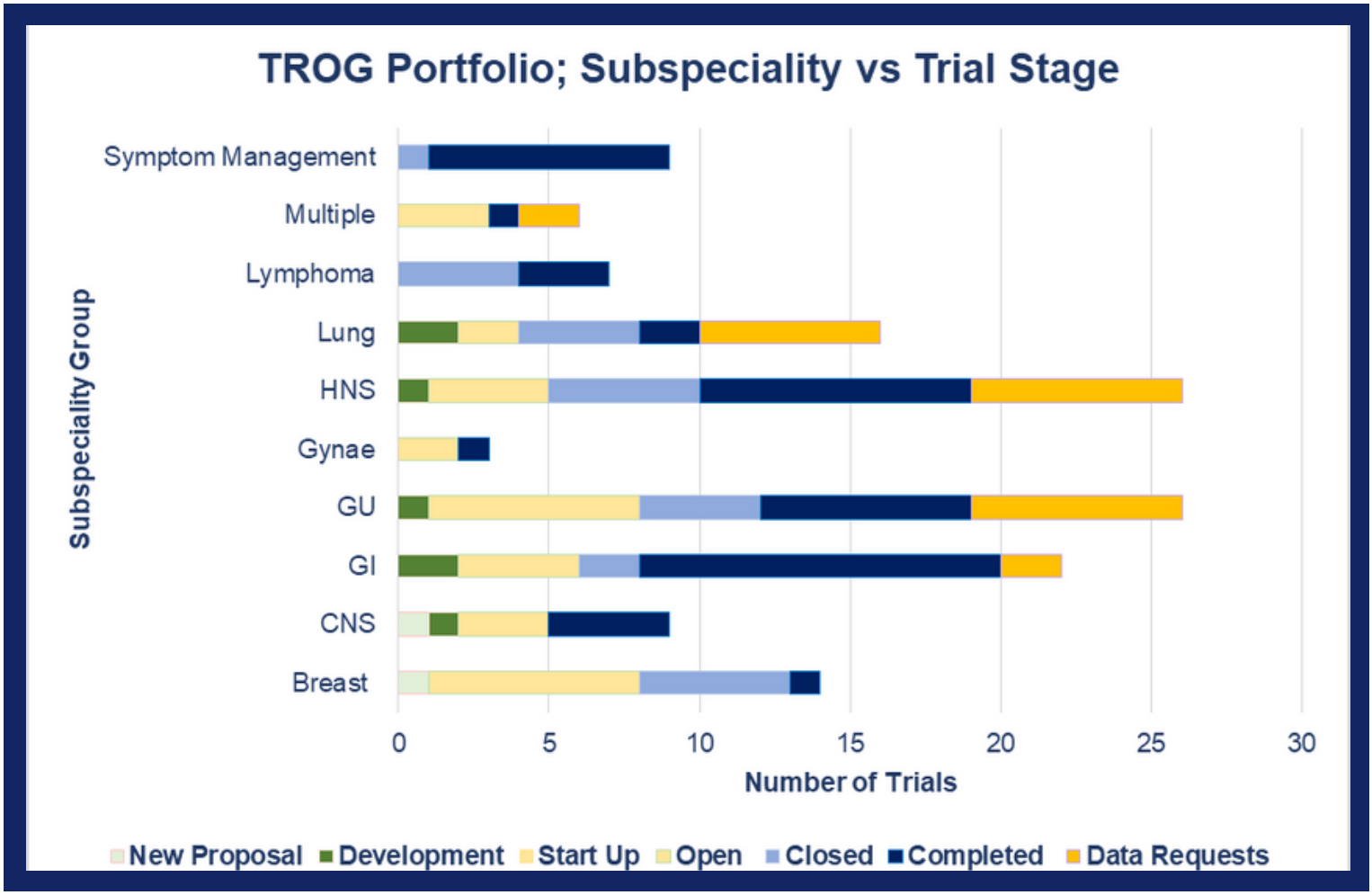
Study Portfolio

TROG Portfolio - Status vs Category (31 December 2022)

STATUS (Trial stage)	A	B	C	D	TOTALS
New proposal (1%)	1	1	0	0	2
Development (7%)	4	1	4	1	10
Open (22%)	14	6	12	0	32
Closed (18%)	17	4	4	0	25
Completed (35%)	38	8	2	0	48
Data Requests (17%)	0	0	0	24	24
TOTAL	74	20	22	25	141
WITHDRAWN	13	14	3	3	33

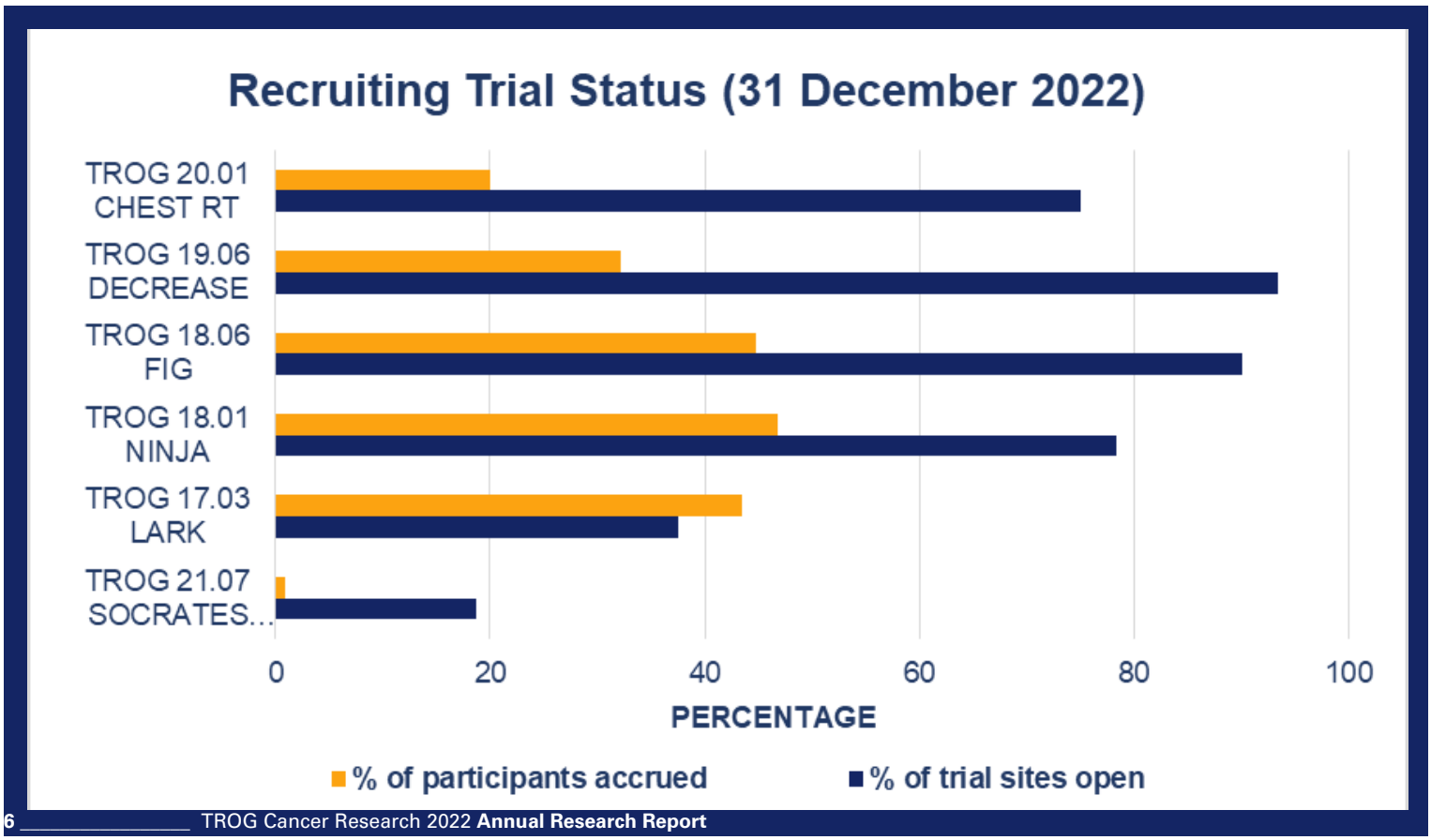
CATEGORY KEY
A: TROG initiated and sponsored trial
B: International trial with TROG as Australian Sponsor
C: Not led by TROG but TROG collaborates with the Sponsor
D: Consists of registries and special projects





Clinical Trial Participant Status

Number of participants in treatment - 2%
Number of Participants in follow-up - 54%
Number of Participants - Completed Trial - 44%



SAHMRI/TROG 21.12 ASPIRE

Assoc Prof. Hien Le

Category A Multiple Cancers

Title: Australian Proton Therapy Clinical Quality Registry (ASPIRE)

Overview

ASPIRE is a prospective, observational, longitudinal study of paediatric, adolescent, young adult and rare adult tumour patients from a select group of tumour streams treated with radiation therapy. The aim of the ASPIRE registry is to enrol >5000 patients who have been treated with radiation therapy in order to better understand and compare the short and long-term benefits of the different types of radation therapy. The information collected will help researchers learn more about radiation treatment.

Sponsor: South Australian Health & Medical Research Institute ((SAHMRT) (Australian Bragg Centre for Proton Therapy and Research parent company))
Supporters: TROG Cancer Research
Funded by: Hospital Research Foundation Group grant
Status at 31/12/2022; Opened; 27 March 2022 | Sites activated; 1 | Accrual; 18
Registry: ANZCTR, ACTRN12622000026729
Website: https://www.protontherapy.sahmri.org.au/about-aptcqr/

Study email: APTCQR@sahmri.com

TROG 21.07 SOCRATES HCC

Assoc Prof. David Pryor & Prof. Alan Wigg

Category A Gastrointestinal

Title: A randomised controlled trial of Standard Of Care versus RadioAblaTion in Early Stage HCC

Overview

Hepatocellular carcinoma (HCC) has one of the fastest rising incidence and mortality rate of any cancer, however, treatment options remain limited and 5-year survival is poor. Unlike most other cancers, the majority of people presenting with early-stage HCC are unable to receive curative intent local therapies or may progress following initial treatment with thermal ablation or transarterial therapies. Emerging data supports a role for stereotactic ablative body radiotherapy (SABR) as a well-tolerated, non-invasive treatment with high rates of local control with some centres now considering it a new standard of care. However, randomised evidence comparing the various treatment options in the first line setting is lacking and the majority of guidelines do not currently endorse its use leading to highly variable utilisation around Australia and internationally. SOCRATES HCC seeks to address this evidence gap by comparing SABR to other current first line treatments (thermal ablation, transarterial therapies) for non-surgical candidates with solitary (≤5cm) early-stage HCC.

SOCRATES HCC aims to set a new benchmark in the management of HCC, improving access to effective curative intent therapies and enhancing inter-disciplinary collaboration.

Sponsor: TROG Cancer Research
Collaborators: Australasian Gastro-Intestinal Trials Group (AGITG)
Supporters: Abdominal Radiology Group of Australia and New Zealand (ARGANZ) & Gastrointestinal Society of Australia (GESA)
Funded by: Medical Research Future Fund (RCRDUN | 2021)
Status at 31/12/2022; Opened; 10 October 2022 | Sites activated; 3 of 17 | Accrual; 2 of 218
Registry: ANZCTR, ACTRN12621001444875

Study email: SOCRATES_HCC@trog.com.au

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Study Portfolio

TROG 20.01 CHEST RT

Dr. Eric Hau & Assoc Prof. Paul Mitchell

Category A: Lung

Title: CHemotherapy and immunotherapy in Extensive Stage small cell lung cancer with Thoracic RadioTherapy (CHEST RT)

Overview

CHEST RT is investigating the safety and effectiveness of combining chemotherapy and immunotherapy with chest radiation therapy for the treatment of extensive stage small cell lung cancer (ES-SCLC). For over 20 years, a combination of chemotherapy using etoposide with either cisplatin or carboplatin had been used to treat ES-SCLC. Adding immunotherapy to the chemotherapy combination has been shown to help boosts the body's natural defences to fight cancer, improving response to treatment. This combination of chemotherapy with immunotherapy is now the standard of care treatment. Research has shown that radiation therapy also improves the ability of the immune system to recognise tumours. The researchers are investigating whether combining radiation therapy with the standard chemo/immunotherapy may further improve patients response to treatment.

Sponsor: TROG Cancer Research
Collaborators: Thoracic Oncology Group of Australasia (TOGA)
Funded by: AstraZeneca; (Externally Sponsored Scientific Research grant)
Status at 31/12/2022; Opened; 11 November 2021 | Sites activated; 6 of 8 | Accrual; 2 of 218
Registry: ANZCTR, ACTRN12621000586819

Study email: CHESTRT@trog.com.au

TROG 19.06 DECREASE

Assoc Prof. Shankar Siva & Assoc Prof. Arun Azad

Category A Genitourinary

Title: DarolutamidE + Consolidation RadiothErapy in Advanced proStatE cancer detected by PSMA

Overview

In the era of PET imaging, many sites of disease that are not visible on conventional imaging (such as CT scans) will be found on Prostate Specific Membrane Antigen (PSMA)-PET scans. These macroscopic sites of disease are the main cause of cancer progression after completing androgen deprivation therapy for prostate cancer. Darolutamide is an indicated treatment for men with Non-Metastatic Castrate Resistant Prostate Cancer (M0 CRPC) with an increasing PSA level. Radiation therapy to sites of disease that have not completely resolved after a few months of drug therapy has been shown to improve patient outcomes, including longevity, in other cancers like lung cancer. With the evolution of PSMA PET scanning, in prostate cancer, there is a unique opportunity to replicate these findings in low-volume prostate cancer. In 87 men with castration-resistant prostate cancer with no evidence of metastases on conventional imaging but detectable disease on PSMA-PET/CT scan, the DECREASE trial will compare the treatment outcomes of men taking Darolutamide with or without treating the small metastasis seen on the PSMA PET scan with radiation therapy. Led by Assoc Prof. Shankar Siva and Assoc Prof. Arun Azad, DECREASE aims to evaluate if the combination (Darolutamide + RT) is better than Darolutamide alone at controlling PSA levels and further spread of prostate cancer. The DECREASE trial, if successful, will meaningfully extend disease control in men receiving Darolutamide.

Sponsor: TROG Cancer Research
Collaborators: Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
Funded by: Bayer (Investigator-Initiated Research grant).
Status at 31/12/2022; Opened; 02 June 2021 | Sites activated; 14 of 16 | Accrual; 28 of 87
Registry: ClinicalTrials.gov, NCT04319783

Study email: DECREASE@trog.com.au

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Study Portfolio

TROG 18.06 FIG

Assoc Prof. Eng-Siew Koh & Prof. Andrew Scott

Category A Central Nervous System

Title: Prospective, multicentre trial evaluating FET-PET In Glioblastoma

Overview

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, as well as determining the accuracy and management impact of FET-PET in distinguishing pseudoprogression from true tumour progression and / or tumour recurrence.

Sponsor: TROG Cancer Research
Collaborators: The Australasian Radiopharmaceutical Trials Network (ARTnet) and The Cooperative Trials Group for Neuro-Oncology (COGNO)
Funded by: Medical Research Future Fund, Cure Brain Cancer Foundation and the Australian Brain Cancer Mission / Cancer Australia
Status at 31/12/2022; Opened; 14 December 2021 | Sites activated; 9 of 10 | Accrual; 94 of 210
Registry: ANZCTR, ACTRN12619001735145

Study email: FIG@trog.com.au

TROG 18.01 NINJA

Prof. Jarad Martin & Dr. Mark Sidhom

Category A Genitourinary

Title: Novel Integration of New prostate radiation schedules with adJuvant Androgen deprivation

Overview

In men with intermediate and high-risk prostate cancer, the NINJA trial is looking at comparing two different radiation therapy treatment schedules called stereotactic body radiotherapy (SBRT). The aim is to develop better methods of treatment for prostate cancer using this type of treatment, and further understand what causes some of the side effects of treatments. It is hoped this research will potentially improve the accuracy and quality of radiation therapy treatment in prostate cancer.

Sponsor: TROG Cancer Research
Collaborators: Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP).
Funded by: Investigator Initiated grant from Mundipharma, Cancer Australia PDRC Grant, investigator funds and in-kind support from recruiting sites.
Status at 31/12/2022; Opened; 16 January 2019 | Sites activated; 18 of 23 | Accrual; 221 of 472
Registry: ANZCTR, ACTRN12618001806257

Study email: NinjaTrial@calvarymater.org.au

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Study Portfolio

USYD/TROG 17.03 LARK

Dr. Yoo Young (Dominique) Lee & Assoc Prof. Tim Wang

Category A: Multiple Cancers

Title: Liver Ablative Radiotherapy utilising Kilovoltage intrafraction monitoring (KIM)

Overview

Stereotactic Ablative Body Radiotherapy (SABR) is an established treatment for both primary and secondary liver malignancies and is a highly effective treatment, but precise dose delivery is challenging due to organ motion. Currently, there is a lack of widely available options for performing real-time tumour localisation to assist with accurate delivery of liver SABR. This study will provide an assessment of the impact of Kilovoltage Intrafraction Monitoring (KIM) as a potential solution for real-time image guidance in liver SABR. It is hoped that this information will improve cancer targeting accuracy and lead to better patient outcomes in the future.

Sponsor: University of Sydney
Collaborators: TROG Cancer Research
Funded by: NHMRC
Status at 31/12/2022; Opened; 16 October 2019 | Sites activated; 3 of 7 | Accrual; 20 of 46
Registry: ClinicalTrials.gov, NCT02984566

Study email: LARK@trog.com.au

TROG 17.01 OUTRUN

Dr. Fiona Hegi-Johnson, Assoc Prof. Chee Khoon Lee & Dr.Yu-Yang Soon

Category A: Lung

Title: A randomised phase II trial of Osimertinib with or without stereotactic radiosurgery for EGFR mutated Non-Small Cell Lung Cancer (NSCLC) with brain metastases (OUTRUN)

Overview

20-40% of patients with advanced NSCLC with EGFR mutation will develop brain metastases during the course of their disease and there are many different ways these brain metastases can be treated including neurosurgery, whole brain radiotherapy, Stereotactic Radiosurgery (SRS) and medication. Research studies have shown that mutations to the EGFR may mean that patients with metastatic NSCLC may respond better to certain types of medications called tyrosine kinase inhibitors (TKIs), such as Osimertinib. Stereotactic radiosurgery (SRS), a specialised radiotherapy technique in which sophisticated technology is used to deliver large radiation doses to the brain metastases, is one of the standard local treatments for patients with limited number of brain metastases. This study aims to determine how well these brain metastases can be controlled by a medication called Osimertinib, given with or without Stereotactic Radiosurgery (SRS).

OUTRUN completed accrual of 40 participants in September 2022 from 12 sites across Australia and Singapore and participants will continue to be followed up until Quarter 3, 2023. Once closed, the data from this trial will be combined with the Canadian BC Cancer Agency's LUOSCINS trial to answer the questions 1) How effective is SRS followed by Osimertinib compared to Osimertinib alone on delaying intracranial disease progression in patients with EGFR mutated NSCLC with brain metastases and 2) Are there subgroups of patients that would benefit more or less from the addition of upfront SRS treatment? This collaboration has been called STARLET.

Sponsor: TROG Cancer Research
Collaborators: Thoracic Oncology Group of Australasia (TOGA)
Funded by: AstraZeneca; (Externally Sponsored Scientific Research grant)
Status at 31/12/2022; Recruitment completed September 2022, participants in follow-up
Registry: ClinicalTrials.gov, NCT03497767

Study email: OUTRUN@trog.com.au

TROG 19.06 trial

DECREASE

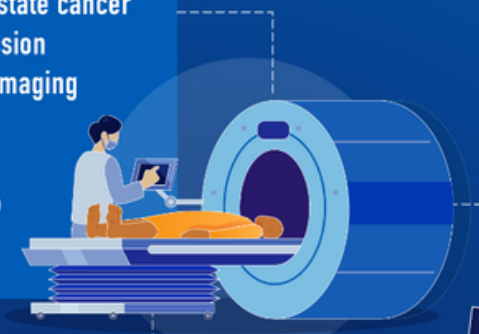
DarolutamidE + Consolidation RadiothErapy in Advanced proStatE cancer detected by PSMA

TROG CANCER RESEARCH

Trial schema

87 patients with castrate-resistant prostate cancer (CRPC) and no progression detected by standard imaging

- Testosterone < 0.6 ng/dL
- PSA progression (incl. PSA ≥ 2 ng/mL & PSA doubling time ≤ 10mths)
- No evidence of metastases on CT C/A/P or WBBS (M0)



Disease detected on PSMA PET

No disease detected on PSMA PET → screened out

RANDOMISED

1/2

1/2

Darolutamide (600mg twice daily)

Darolutamide (600mg twice daily)

Additional PSMA PET 12 weeks post-randomisation

Local consolidation radiotherapy

targeting up to 5 sites of the disease

Continue on **Darolutamide**

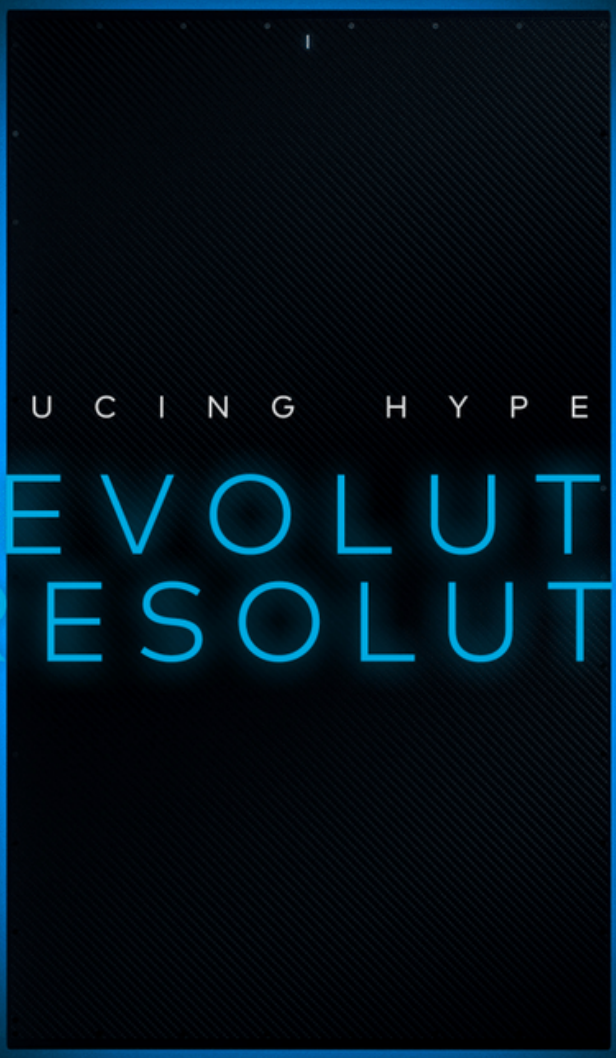
with regular assessments: WBBS, CT and blood tests

Follow up until radiological progression

confirmed by PSMA PET: Radium 223 available at investigator discretion

Recruiting Category C trials

Subspeciality	Primary Sponsor	Trial Number	Trial Acronym	Study Title	TROG tracking number
Gynaecological	Australia New Zealand Gynaecological Oncology Group (ANZGOG)	ANZGOG 1910/2020	ADELE	ADjuvant tislelizumab plus chemotherapy after post-operative pelvic chemoradiation in high-risk EndometriaL cancer (ADELE): a randomised phase 2 trial	21.04
Gastrointestinal	Australasian Gastro-Intestinal Trials Group (AGITG)	AGITG	RESOLUTE	Randomised phase II trial to Evaluate the Strategy Of integrating Local ablative Therapy with first-line Systemic Treatment for UnresecTablE Oligometastatic Colorectal Cancer	21.03
Genitourinary	Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)	ANZUP 1801	DasI-HiCaP	Darolutamide Augments Standard therapy for Localised very HIgh-risk Cancer of the Prostate (ANZUP1801). A randomised phase 3 double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high risk, clinically localised prostate cancer.	21.02
Head and Neck	Melanoma and Skin Cancer Trials (MASC)	MASC 03.18	I-MAT	A randomised, placebo-controlled, phase II trial of adjuvant Avelumab in patients with stage I-III Merkel cell carcinoma	21.01
Breast	Peter MacCallum Cancer Centre	17/013	AVATAR	A randomised phase II trial comparing the efficacy of single fraction or multi-fraction SABR (Stereotactic ablative body radiotherapy) with Atezolizumab in patients with adVAnced Triple negative breAst CanceR	20.03
Gastrintestinal	Australasian Gastro-Intestinal Trials Group (AGITG)	CTC 0245/ AGITG AG0118PS	MASTERPLAN	Randomised phase II study from the AGITG Mfolfirinox And STEreotactic Radiotherapy for Pancreatic cancer with Locally AdvaNced disease	18.04
Skin	Regeneron Pharmaceuticals	R2810-ONC-1788	CPOST	A randomised, placebo-controlled, double-blind study of adjuvant Cemiplimab versus placebo after surgery and radiation therapy in patients with high risk cutaneous squamous cell carcinoma	17.11
Breast	Breast Cancer Trials (BCT)	ANZ 1601/ BIG 16-02	EXPERT	A randomised phase III trial of adjuvant radiotherapy versus observation following breast conserving surgery and endocrine therapy in patients with molecularly characterised low-risk luminal A early breast cancer (EXPERT)	16.04



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