CREST
CANCER RESEARCH ECONOMICS SUPPORT TEAM
www.crest.uts.edu.au

CHERE
CENTRE FOR HEALTH ECONOMICS RESEARCH AND EVALUATION

CENTRE FOR HEALTH ECONOMICS RESEARCH AND EVALUATION

CREST Update—June 2020

Determinants of health-related quality of life: disagreement between caregivers proxy ratings for children with cancer

Parent proxy reports of children's health-related quality of life (HRQoL) are often used in paediatric oncology; such reports are crucial in circumstances where children are too young, cognitively impaired, or too ill to complete an HRQOL instrument by them- selves. In using proxy ratings, it is common to ask just one parent to report on the child, most often the mother. However, it is unknown if there are systematic differences between caregivers in their proxy HRQoL ratings. Such differences may affect the interpretation and application of parent-reported outcomes. This can be particularly important if those ratings are going to inform estimates of quality of life ratings included in economic evaluations based on quality adjusted life years.

Rensen et al. (2020) recently conducted a study to compare paternal and maternal proxy reports and explored the determinants of couple (dis)agreement in ratings (1). Both parents completed the Paediatric Quality of Life InventoryTM (PedsQL generic; child's HRQoL), Short Form-12 (own QoL) and Distress Thermometer for Parents. Intra-class correlation coefficients (ICCs) were calculated to assess agreement in paternal and maternal proxy HRQoL scores, with differences assessed using paired t-tests and visualised using Bland– Altman plots. Multiple logistic regression analysis was used to explore the characteristics of parental couples with a mean proxy difference in the highest quartile (highest proxy score minus lowest proxy score).

A total of 120 parental couples (120 mothers and 120 fathers) with a child with cancer (87% post-treatment, mean age 11.0 ± 5.7 years) participated in this study. The authors found no significant differences between paternal and maternal proxy scores, with a good level of agreement on all scales (ICCs 0.65–0.83; Table 1). Further, the Bland–Altman plots did not reveal any systematic disagreement patterns, although there was a wide range in magnitude of the differences (in both directions).

For determinants of caregiver disagreement, couples with a mean proxy difference (irrespective of which direction) in the highest quartile differed an average 20 points. That is, approximately 25% of parents reported their child's HRQoL somewhat differently. These couples were more likely to have a child in active treatment or with a relapse, have a child with retinoblastoma, and to diverge in their own mental QoL—compared to the parental couples with a proxy difference in the lower three quartiles (a difference between 0 and 10 points on most scales).

The authors noted that if possible, proxy reports of both parents should be included, since it was shown that 25% of parents differed widely in their scores. Despite this difference, the paper concluded that clinicians/researchers may reasonably assume that paternal and maternal reports are interchangeable.

1. *Rensen, N et al. (2020). Determinants of health-related quality of life proxy rating disagreement between caregivers of children with cancer. Quality of Life Research, 29(4), 901–912.*

Contributed by Terence Khoo

Proxy-rated HRQoL scale	Parents of healthy children (n=618–711) [21]	Fathers of children with cancer (n=95–113)	Mothers of children with cancer (n=95–113)	Parental agreement (oncology sample)	Mean difference father–mother (SD)	ES
	Mean (SD)	Mean (SD)	Mean (SD)	ICC [95% CI]		
Total HRQoL	87.6 (12.3)	80.1 (17.6)*	79.1 (18.0)*	0.83* [0.76, 0.88]	0.97 (10.4)	0.05
PSHS	86.6 (12.8)	79.2 (17.2)*	77.6 (17.8)*	0.78* [0.68, 0.85]	1.66 (11.7)	0.09
Physical functioning	89.3 (16.4)	80.9 (22.3)*	81.6 (22.2)*	0.83* [0.76, 0.88]	-0.68 (13.0)	0.03
Emotional functioning	82.6 (17.5)	74.4 (22.3)*	72.1 (21.9)*	0.80* [0.71, 0.86]	2.28 (14.0)	0.10
Social functioning	91.6 (14.2)	82.0 (18.6)*	80.4 (20.1)*	0.65* [0.53, 0.74]	1.64 (16.3)	0.08
School functioning	85.5 (17.6)	79.9 (20.2)*	78.0 (21.6)*	0.67* [0.54, 0.76]	1.95 (17.1)	0.09

PSHS Psychosocial Health Summary Score, *ES* effect size (Cohen's *d*)
*p<0.001; indicating a significant difference with parents of healthy children

Table 1: Proxy HRQoL ratings of mothers and fathers of children with cancer: differences with healthy children and level of parental agreement

Contact the Cancer Research Economics Support Team:
http://www.crest.uts.edu.au

Richard De Abreu Lourenço: +61 (2) 9514 4729
Richard.deabreulourenco@chere.uts.edu.au

Nancy Kim: +61 (2) 9514 4733
Nancy.kim@chere.uts.edu.a

Australia and New Zealand Sarcoma Association (ANZSA)

While COVID-19 is a challenging time for many, the Australia and New Zealand Sarcoma Association (ANZSA) continues to operate as usual with our research and clinical trials priorities.

The ANZSA Board and the ANZSA Annual Scientific Meeting (ASM) Organising Committee has decided to transition the ANZSA 2020 ASM scheduled for October in Melbourne to a virtual meeting (video conferencing) so that the organisation can still share updates and progress with the sarcoma community.

The decision to not have a face-to-face meeting is a precautionary measure for the health and wellbeing of our delegates – many of whom are international and interstate travellers.

Stay tuned for more details on the date and agenda of the meeting.

Excitingly, as part of this year's Sarcoma Awareness Month in July, ANZSA is organising a series of four webinars covering a range of topics for healthcare professionals and consumers. The four topics and dates include:

- 6 July – Clinical Trial – Why I Should Participate in One
- 16 July – Managing the Practical Issues whilst Undergoing Sarcoma Treatment
- 23 July – Survivorship – Life After Treatment
- Sarcoma Patient Referral Pathway (date to be confirmed)

These topics were chosen in consultation with our Consumer Advisory Panel (CAP), and we hope you can join us for the webinars. For more information, follow us on Facebook (ANZSarcoma) and Twitter (@anzsarcoma).

While many clinical trials were affected by COVID-19, all ANZSA clinical trials have managed to continue with little disruption. We are thankful that all the clinicians and patients were quick to adapt to the changes.

We have three ongoing projects open for patient recruitments:

- SARC032 – A Phase II randomised controlled trial of neoadjuvant pembrolizumab with radiotherapy and adjuvant pembrolizumab in patients with high-risk, localised soft tissue sarcoma of the extremity.
- NORTH – A Phase II study of panobinostat in paediatric adolescent and young adult patients with solid tumours including osteosarcoma, malignant rhabdoid tumour and neuroblastoma. This clinical trial is funded by the NH&MRC and jointly run with ANZCHOG. It is now open for patient recruitment in 14 sites across Australia.
- rEECur – International randomised controlled trial of chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma. This clinical trial is funded by a grant from CanTeen and is now open for patient recruitment in both adult and paediatric sarcoma centres across ANZ. It is now open for patient recruitment in 11 sites across Australia.

For more details about the projects, site locations or want to be involved in the patient recruitment process, write to us contact@sarcoma.org.au or visit sarcoma.org.au/projects.

We are also proud to announce the funding of two Australian researchers for our ANZSA 2020 Sarcoma Research Grants:

The Johanna Sewell Sarcoma Research Grant was awarded to Dr James Blackburn from the Garvan Institute of Medical Research. Dr Blackburn's research will look to improve fusion gene detection and immune response assessment in sarcoma patients.

The Xavier Krikori Sarcoma Research Grant was awarded to Dr Rachael Terry from the Children's Cancer Institute, Lowy Cancer Research Centre at the University of New South Wales and Prince of Wales Hospital. Dr Terry's research will look into new immunotherapy strategies for paediatric rhabdomyosarcomas.

While we continue to navigate through the challenges of COVID-19, we are looking ahead to a productive next half of the year. We are thankful for our patients, collaborators, donors and members for their continued support, generosity and trust in us and the work we do despite the challenges. We are all in this together.

Contributed b Dr Denise Caruso, CEO of ANZSA

Breast Cancer Trials

COVID-19 Update

The dynamic situation around the COVID-19 pandemic seems to have eased and while conducting clinical trials is by no means normal, we are continually assessing how to approach each individual clinical trial to ensure the safety of trial participants, whilst maintaining compliance with GCP and minimising risks to trial integrity. Trial specific communications have been developed and circulated. Updates will continue to be forwarded, as and when necessary. Many institutions initially took the precautionary step to suspend recruitment to all trials and are now commencing discussions to reinstate recruitment activities where possible in the current COVID-19 pandemic.

Concept Development Workshop

Despite the cancellation of the Breast Cancer Trials Annual Scientific Meeting, a virtual Concept Development Workshop and Scientific Advisory Committee (SAC) meeting will be held on 24 July 2020. The Concept Development Workshop is aimed at providing an opportunity for investigators to present new research ideas to SAC members and other members skilled in conducting trials to receive feedback and suggestions/support to further develop their concept. The date for concept submissions has now closed.

Blogs and Podcasts

Over recent months, Breast Cancer Trials has been producing a number of blogs and podcasts on the topic of COVID-19, which are available on the BCT website at www.breastcancertrials.org.au/research-blog.

- Board Director, Associate Professor Nicholas Wilcken, and member of the Scientific Advisory Committee (SAC), Professor Fran Boyle AM, provided an insight into working in the new COVID-19 environment for health professionals and BCT members.

Nicholas Wilcken, Fran Boyle

- We asked several BCT members to tell us how life has changed in their hospitals due to COVID-19 and how they are looking after patients. Dr Janine Lombard and Professor Fran Boyle AM, both members of SAC, and Ms Vicki Sproule, a clinical trials coordinator, share their experience.
- Incoming member of the Consumer Advisory Panel, Ms Tracey Lewis, has metastatic breast cancer and shared why social distancing is important to her and her family.

Tracey Lewis and family

- Marie Pandeloglou is currently undergoing treatment for stage IV breast cancer, which has spread to her liver, lungs and brain. Marie is a past participant in our IMPACT Advocate program, which enabled her to attend our Annual Scientific Meeting to learn more about clinical trials research. She shared how her treatment has changed in the current COVID-19 environment and the precautions that both she and her treatment team have been taking.

Marie Pandeloglou and family

Contributed by Anna Fitzgerald

How are patient-reported outcomes and symptoms being measured in adults with relapsed/refractory multiple myeloma? A systematic review

Patients with relapsed and/or refractory multiple myeloma (RRMM) have experienced an improvement in survival over the past decade due to advancements in treatments. However, it is also crucial to understand the impact different treatments have on the quality of life of these patients. Research suggests that health outcomes directly reported patients are the best way to measure patients' perceptions of their health concerning a specific disease and its treatment. Health outcomes assessments, particularly quality of life, are a critical input to economic evaluations which seek to assess the value of therapies based on assessing the cost per quality adjusted life year – the combination of the length and quality of life

LeBlanc et al. (2020) recently conducted a systematic review to summarise the evidence and reporting quality for patients' experience collected through patient-reported outcomes (PRO) in RRMM patients (2).

Table 1: Patient-reported outcomes (PROs)

	PROs assessed	PROs reported	PRO measures
PRO Domains			
Emotional function	26	11	EORTC QLQ-C30[a] EORTC QLQ-MY20[b] FACT-G[c] MyPOS[d]
Global health satus/QoL	19	16	EORTC QLQ-C30 FACT-G EuroQol 5D[e]
Physical function	16	14	EORTC QLQ-C30 FACT-G
Social function	16	10	EORTC QLQ-C30 FACT-G
Financial burden	16	6	EORTC QLQ-C30 Financial burden
Role function	15	8	EORTC QLQ-C30
Cognitive function	15	8	EORTC QLQ-C30
Symptom index	12	8	EORTC QLQ-MY20 FACT-G MyPOS MDASI-MM[f]
Healthcare factors	2	2	Financial burden MyPOS
Individual symptoms			
Pain	20	15	BPI-SF[g] EORTC QLQ-C30 NRS pain[h] VAS pain[i]
Fatigue	18	11	EORTC QLQ-C30 FACIT fatigue[j]
Dyspnea	15	8	EORTC QLQ-C30
Constipation	15	7	EORTC QLQ-C30
Nausea/vomiting	15	7	EORTC QLQ-C30
Diarrhea	15	6	EORTC QLQ-C30
Appetite loss	15	6	EORTC QLQ-C30
Sleep disturbance	15	6	EORTC QLQ-C30
Peripheral neuropathy	8	8	EORTC QLQ-CIPN20[k] FACT/GOG-NTX[l]

PRO reporting quality was assessed using the Consolidated Standards of Reporting Trials (CONSORT) PRO Extension checklist.

The systematic review identified 30 manuscripts representing 23 individual studies. Across these studies, 13 unique PRO measures were administered to assess nine PRO domains and nine individual symptoms. Individual symptoms refer to specific physical or emotional effects of RRMM or its treatment, while PRO domains refer to more integrated concepts (e.g. symptom indexes or functioning). The authors found that pain and emotional function were the most commonly assessed symptom and PRO domain, respectively (Table 1). The authors noted that the majority of manuscripts re- ported change in PRO scores without reporting baseline values and/or prevalence data; which limited the ability to understand the prevalence and severity of PRO challenges in RRMM.

Criteria	Manuscripts meeting criteria $n = 30$ (%)
1. PRO identified in abstract as primary or secondary outcome	22 (73.3)
2. Background and rationale for PRO assessment	18 (60.0)
3. PRO hypothesis stated	3 (10.0)
4. Relevant domains identified	21 (70.0)
5. Present evidence and/or reference of reliability and validity for PRO instruments	15 (50.0)
6. Person completing PRO specified	17 (56.7)
7. Method of administration specified	5 (16.7)
8. Assessment timepoints specified	27 (90.0)
9. Statistical methods for analyzing PRO data specified	18 (60.0)
10. Statistical approaches for missing data specified	7 (23.3)
11. Number of PRO participants at each timepoint reported	12 (40.0)
12. Baseline PRO data reported	16 (53.3)
13. PRO results for all domains reported	22 (73.3)
14. PRO specific limitations and implications for generalizability and clinical practice	8 (26.7)
15. Patient-reported outcome data are interpreted in relation to clinical outcomes including survival data	28 (93.3)

CONSORT PRO consolidated standards of reporting trials patient-reported outcomes. patient-reported outcome.

Table 2: CONSORT PRO extension criteria

The review found that overall, the PRO reporting quality in RRMM studies was suboptimal and inconsistent. The most commonly adhered to items from the CONSORT PRO criteria checklist were 'PRO data is interpreted in relation to clinical outcomes' (93%) and 'Assessment timepoints specified' (90%); while the least commonly adhered to were 'PRO hypothesis stated' (10%) and 'Method of questionnaire administration specified' (17%) (Table 2).

The authors concluded that existing PRO evidence was mainly from clinical trials with suboptimal reporting quality. Observational studies are needed to describe prevalence, severity and patterns of PROs in RRMM overtime. Future studies that incorporate PROs should follow existing guidelines so that those who seek to use PROs can fully assess the study evidence and conclusions. This is critical for economic evaluations whose results can be highly sensitive to the quality of PRO assessment and reporting.

1. *Cancer Australia 2019, Myeloma in Australia statistics, accessed June 2020, https://myeloma-cancer.canceraustralia.gov.au/statistics*
2. *LeBlanc, MR et al. (2020). How are patient-reported outcomes and symptoms being measured in adults with relapsed/refractory multiple myeloma? A systematic review. Quality of Life Research, 29(6): 1419–1431.*

Contributed by Terence Khoo

Sydney Quality of Life Office

The Sydney QOL Office is happy to introduce our new team member, Dion Candelaria.

Dion is the new Quality of Life Research Associate. He previously held an Associate Lecturer position-Clinical Education Specialist position at The University of Sydney Susan Wakil School of Nursing and Midwifery. He is currently completing his PhD at the University of Sydney on health-related quality of life outcomes in patients attending cardiac rehabilitation. His research project aims to identify vulnerable population groups and develop patient-centred interventions. His research interests include improving the quality of health services through the integration of patient-reported outcome measurement in clinical practice and ensuring that interventions are responsive to individual patient needs. Dion looks forward to working with the Sydney QOL Office team providing the QOL-Technical Service.

All Cancer Clinical Trial Group members and staff can access the Sydney Quality of Life Office resources available online. If you have any queries, the best way to contact us directly is via our online query form or by email.

We also recommend new staff, and new investigators considering collecting PROs in their studies, have a look at our short introductory presentation on PRO terms and definitions. When prompted, please enter this access code: QOL-TS

All the best,

Sydney Quality of Life Office

Contributed by Margaret-ann Tait

SQOLO
Sydney Quality Of Life Office

CREST Workshops

CREST Workshop videos – Now available on the CREST website.

As part of its capacity-building services for the Cancer Australia Collaborative Clinical Trials Groups (CTGs), CREST holds several health economics focused workshops each year.

Members of CTGs can access the material discussed at workshops; each workshop has been provided as a series of short videos produced from the material presented.

Topics currently available on the website include:

- Understanding health economics in cancer research
- Preferences in Cancer Trials – What Choices can tell us About Value
- Health Economics in Cancer Research – A Consumers' Guide

To access these videos please visit uts.edu.au/crest-training-videos

Cooperative Trials Group for Neuro-Oncology (COGNO)

COGNO COOPERATIVE TRIALS GROUP FOR NEURO-ONCOLOGY

While the past few months have been challenging, it is business as usual in the new normal for COGNO. Our ASM and workshops are rescheduled or recast as virtual events, recruitment continues for some trials, and work is ongoing with trials in development.

It is an exciting time at COGNO with LUMOS, a pilot study testing the feasibility of providing access to molecular testing for patients with progressive low grade (grade 2) and intermediate grade (grade 3) glioma. The aim is to identify actionable mutations that may be amenable to targeted treatments. These patients do well initially but their tumours inevitably relapse and survival is very poor thereafter. Unfortunately, clinical trials are very difficult to access for this patient. LUMOS is an Australian trial that was specifically designed for these patients with the aim to match tumours on a molecular level with the best available treatments. The pilot study will be recruiting across five centres with a minimum target of 10 participants. The study opened for recruitment on 21 April 2020 at Austin Health and immediately enrolled a patient. Currently, LUMOS is open at two locations in Victoria including Olivia Newton-John Cancer Research and Wellness and Peter MacCallum Cancer Centre with three more locations to shortly open at St Vincent's Hospital (NSW), Royal Brisbane and Women's Hospital (QLD) and Sir Charles Gairdner Hospital (WA).

Key to the design of full LUMOS study is the integration of health economics evaluations, which has been undertaken in collaboration with CREST. The analysis of outcomes will focus on producing an estimate of the combined impact of treatment on survival and quality of life using the QLU-C10D. A modelled analysis will be developed using existing data on treatments in low and intermediate glioma patients to assess the cost-effectiveness of targeted therapies in this clinical context. The lead investigator, Professor Hui Gan, stated, "Given the paucity of trials in low and intermediate grade gliomas, this economic data will be vital to ensure such drugs are funded by governments if the study confirms their clinical benefit".

Please email lumos@ctc.usyd.edu.au if you would like any further information.

Contributed by Jenny Chow

Cancer Symptom Trials (CST) — Survey

Cancer symptom management priority setting - adult

You are invited to participate in a survey study which is aiming to identify the key research questions which should be addressed as a priority to improve the management of symptoms related to cancer and its treatment.

We are interested in your views regarding which cancer symptoms have the biggest impact on daily life for people that are living with or have lived with cancer and those that take care of them. To participate in the survey, go to www.uts.edu.au/cst/cstprojects

Trans-Tasman Radiation Oncology Group (TROG)

TROG Cancer Research excel with virtual Annual Scientific Meeting (ASM)

With COVID-19 changing the way we operate daily, TROG Cancer Research have had to find innovative solutions to keep the ball rolling.

Most significantly, TROG Cancer Research put their creative minds together to take the Annual Scientific Meeting (ASM) virtual for 2020. Across 17-19 March 2020 more than 250 of Australia and New Zealand's leading radiation oncologists, medical oncologists, radiation therapists, medical physicists and clinical trials personnel attended a full program of international and national presentations as well as tumour stream working group discussions by logging in from their home or work office.

Despite limited time to organise the logistics and scheduling, –TROG was able to pivot successfully in the face of COVID-19 and deliver to its members, the annual scientific meeting and the associated opportunities for maintaining momentum with clinical trial activity.

Co-Convenor of the ASM and TROG Board Director, A/Prof Puma Sundaresan said that whilst there was the option to reschedule the event, the live virtual ASM was able to still provide a valuable forum for colleagues to collaborate, share ideas and progress cancer research that can have positive impact globally.

From the attendee records gathered from the live virtual ASM, there was strong engagement from both delegates and sponsors. Almost 220 unique email addresses logged onto the meeting's live stream, with viewer numbers averaging 140 for each session.

The experience of TROG Cancer Research has been published as a peer reviewed, open access manuscript and is available to read in the Journal of Medical Imaging and Radiation Oncology (JMIRO).

Various awards were given out at the TROG 2020 ASM to professionals who have achieved new developments through clinical trials and to those who have shown leadership in their roles.

Professor Paul Keall and Professor Jarad Martin (pictured) were awarded the TROG Trial Excellence Award for their work with the TROG 15.01 SPARK Trial

The trial focused on the Efficacy of Kilovoltage Intrafraction Monitoring (KIM) in men with prostate cancer undergoing stereotactic prostate radiotherapy.

Professor David Christie was awarded the 'Outstanding Contributions to TROG' award for his ongoing work to help transform TROG Cancer Research into an internationally recognised world class clinical trials group.

Over his time with TROG Cancer Research, David has filled many leadership roles including Company Secretary, Scientific Committee member and Chair, Publications Committee Chair and Board Director.

Contributed by Susan Goode

November 2019 APGOT meeting in Singapore.

Melanoma and Skin Cancer Trials (MASC)

Melanoma and Skin Cancer Trials Limited

MASC Trials has continued to operate throughout the COVID-19 period, supporting our members and institutions to get through this challenging time. Our recently established Melbourne team continues to grow and compliments the Sydney team, with all staff seamlessly transitioning to home-based working arrangements in response to recent events. We are pleased to report that MASC Trials has continued to recruit new patients with 92 participants across 6 protocols so far this year.

We would like to warmly invite all members and associates to attend the upcoming MASC Trials Annual Research and General Meeting which will be taking place in virtual format on the 23-24 October 2020 where we will showcase our current and new research activities.

The MASC Trials team are currently finalising approvals for new trials to be opened in coming months, many with integrated health economic measures involving close engagement with CREST and members of their team.

New research which will launch shortly includes the activation of the 07.17 AOMA Uveal Melanoma Registry, 10.17 GoTHAM NCT04261855, 02.18 I-MAT NCT04291885, 02.19 IMAGE NCT04385732, and NRP 11.19 Improving melanoma and skin cancer awareness and outcomes for Australians living in regional and remote areas. Furthermore, we are thankful for the willingness of several sites (in Australia and abroad) who have continued to open protocols during this time.

02.18 MelMarT-II NCT03860883, 02.12 RADICAL ACTRN12615000266561, 01.15 CHARLI ACTRN12617000772347, and 04.17 SMARTI NCT04040114, are now actively recruiting at sites both nationally and internationally. Our research relies on a team effort to support the multi-institutional recruitment oftentimes fundamental to meet sample size targets, and we extend our thanks to our members for their continued support.

We also have several studies that will be analysed soon, and we look forward to disseminating the results of these studies shortly, including; 02.09 Mel-D ACTRN12609000351213, 02.14 Combi-RT ACTRN12615000292572, 01.12 EAGLE-FM ACTRN12614000721606, 01.09 RTN2 ACTRN12610000478011 and 1.07 SS01.13 Hair Spare protocols ACTRN12617000507381.

If you are interested in becoming a MASC Trials member or wish to find out more information about any of our trials, please contact the MASC Trials' team via email to Elizabeth.Sadowy@masc.org.au.

Contributed by Elizabeth Sadowy

What else is CREST up to?

Trial Group Collaborations:

- Attendance at the PC4 Virtual Concept Development Workshops, April/May 2020.
- Attendance at the PC4/PoCoG Concept Development Teleconference, April 2020.
- Attendance at AGITG Lower and Upper GI Working Party Teleconference, May 2020.
- Attendance at various ANZUP Virtual Concept Development Workshops and Subcommittee meetings, May 2020.

Other Activities

- Membership of scientific advisory/steering committees.
- Ongoing correspondence with Clinical Trial Groups.
- Providing ongoing health economic technical support to the Clinical Trial Groups.
- Scheduled meeting with Executive Officers of various Clinical Trial Groups and other Technical support services to discuss Health Economic needs and identify areas of collaboration.

Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)

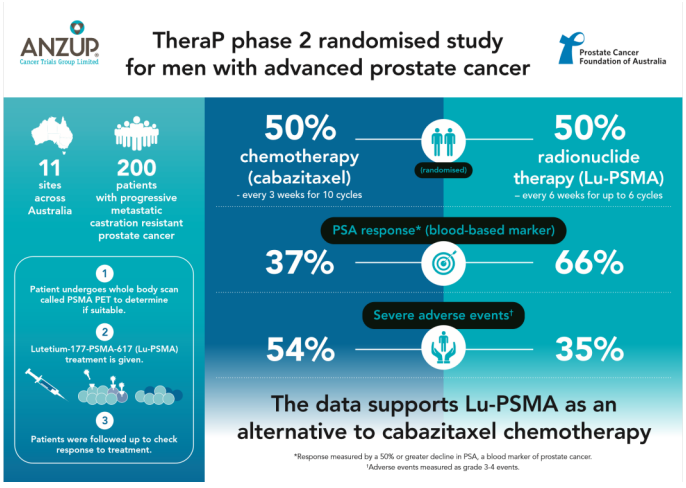
We were delighted to see our TheraP trial (ANZUP 1603) feature as an oral presentation in the ASCO 2020 virtual meeting on Friday 29 May, with Michael Hofman presenting the interim results. TheraP is the first randomised trial comparing 177Lu-PSMA-617 (Lu-PSMA), a novel radioactive treatment, to the current standard-of-care chemotherapy called cabazitaxel for men with metastatic castration-resistant prostate cancer. The University of Sydney's NHMRC Clinical Trials Centre provided central study coordination. TheraP is a partnership between ANZUP and the Prostate Cancer Foundation of Australia (PCFA) with support from the Australian Nuclear Science and Technology Organisation (ANSTO), Endocyte, It's a Bloke Thing, Movember and CAN4CANCER.

Trial News

In April 2020, we activated our DASL-HiCaP trial (ANZUP 1801) and recruited our first patient. DASL-HiCaP is 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.

This study aims to recruit 1,100 patients from over 100 sites across Australia, New Zealand, US, Canada, UK and Ireland. DASL is a collaboration between ANZUP and the Canadian Cancer Trials Group, Dana-Farber Cancer Institute, Prostate Cancer Clinical Trials Consortium and Cancer Trials Ireland. The University of Sydney's NHMRC Clinical Trials Centre will act as the central coordinating centre. Congratulations to Chris Sweeney, Tamim Niazi and the DASL trial team of investigators, site staff and coordinating centres on this achievement.

Our soon to be launched ENZAp trial (ANZUP 1901) is an ANZUP-led randomised phase II trial using PSMA as a therapeutic agent (Lutetium -PSMA) and prognostic indicator (PSMA-PET) in men with metastatic castrate-resistant prostate cancer treated with enzalutamide. This study is being led by Louise Emmett from St Vincent's Hospital in Sydney. The study aims to recruit 160 patients, across 12 sites. #UpFrontPSMA, (ANZUP co-badged) trial is a randomised phase 2 study of sequential 177Lu-PSMA-617 and docetaxel versus docetaxel in metastatic hormone-naive prostate cancer, also randomised its first patient. Congratulations to Arun Azad and Michael Hofman and the entire UpFront team on this achievement.



The TheraP trial interim results infographic

Prof. Michael Hofman interview by Channel Nine news re: the interim results for the TheraP trial.

ANZUP Annual Scientific Meeting (ASM)

Earlier in the year we made the difficult decision to postpone our July 2020 ASM due to COVID-19 and move it to 2021. Our #ANZUP21 will be held from Sunday 18 July to Tuesday 20 July 2020 at the Adelaide Convention Centre.

Due to overwhelming support from our members, we will also be holding a mini-ASM in November in Melbourne. The program is currently being finalised however it will feature the MDT Masterclass, an evening symposium and Best of GU highlights.

Contributed by Nicole Tankard

Australasian Lung Trials Group (ALTG)

The rising incidence of lung cancer, and the use of targeted and immunotherapies will contribute to increased healthcare expenditure in the next decade. Consequently, incorporation of analyses showing health economic benefits into selected ALTG trials, as described below, is critical to ensure translation of clinical trial outcomes into improved healthcare.

ASPiRATION

The ALTG has recently been awarded MRFF funding for the ASPiRATION trial, a sub-program of the Australian Genomic Cancer Medicine Centre's (AGCMC trading as Omico) Molecular Screening and Therapeutics (MoST) study that is co-ordinated through the NHMRC Clinical Trials Centre. ASPiRATION will evaluate the benefit of routine up-front comprehensive genomic profiling (CGP) in 1000 newly diagnosed metastatic, non-squamous, non-small cell lung cancer (mNSCLC) patients in Australia. Currently, mNSCLC patients undergo sequential standard of care testing for EGFR, ALK and ROSI genes to identify targets for specific treatments. However, there are several well-established, and an increasing number of emerging, genomic alterations in mNSCLC patients that are not identified as part of this testing. CGP provides a more sensitive method to simultaneously identify established and emerging actionable molecular disease targets for specific treatments. The ASPiRATION study is designed to flow into treatment-specific pathways (comprising PBS-reimbursed treatment and signal-seeking clinical trials) that enable access to targeted NSCLC treatments and test the hypothesis that, despite the cost of CGP, its implementation into standard diagnostic testing for mNSCLC patients is feasible and results in substantial patient benefits and savings in overall healthcare utilisation.

PEARL

The PEARL study determines if early referral to palliative care should be integrated in Australian health care for patients with recently diagnosed, advanced thoracic malignancies through evaluation of HRQOL, overall survival and cost utility in terms of quality-adjusted life years (QALYs).

DREAM and DREAM3R studies

DREAM and DREAM3R are Phase II and III trials respectively that examine the efficacy of adding immunotherapy to chemotherapy treatment for malignant pleural mesothelioma. The positive outcome of the Phase II DREAM study, (In Press, Lancet Oncology), has led to a successful collaboration with Pre-COG, a US-based clinical trials group, to conduct a Phase III randomised study, referred to as DREAM3R that includes an incremental cost-effectiveness and cost-utility analysis.

The ALTG welcomes trial concept submissions. To submit a concept or participate in peer-review please contact altg@lungfoundation.com.au or see https://altg.com.au/research-overview/trial-development-process/ for more information. Additional information, including how to become an ALTG member and a recent webinar of ASCO2020 thoracic malignancy highlights, can be found at www.altg.com.au.

Contributed by Megan Sanders

ALTG has been successfully awarded more than $12 million to conduct ASPiRATION in a partnership between academia, industry and government.

Australasian Leukaemia and Lymphoma Group (ALLG)

ALLG AUSTRALASIAN LEUKAEMIA & LYMPHOMA GROUP

Better treatments... Better lives.

The Australasian Leukaemia & Lymphoma Group (ALLG) has remained resilient through the COVID-19 pandemic. For the first time in over 20 years, the ALLG May Scientific Meeting shifted from a face-to-face to a virtual format. The expanded meeting from Monday, May 11 through Saturday, May 16, was a resounding success, with over 400 ALLG Members, staff and supporters attending the week-long event.

The Welcome/Opening Session saw a range of pre-recorded messages from the Chair of the ALLG Scientific Advisory Committee A/Prof Peter Mollee, Chair of the ALLG Member Relations Working Group Dr Robert Weinkove and a range of guest speakers including Mr Anthony Carbines MP, Victorian Parliamentary Secretary for Health and Parliamentary Secretary for Carers and Volunteers, Prof Anne Kelso AO CEO of the NHMRC, A/Prof Kate Stern Onco-Fertility Specialist and a range of international clinical trial collaborators.

The ALLG held several innovative sessions, including a combined HSANZ-ALLG Supporting Members with Resilience and Coping Techniques in Challenging Times, with Prof Michael Reade AM discussing leadership and teamwork, Dr Monique Crane presenting on psychological resilience and Pauline McKinnon discussing Meares' medical approach to 'stillness.' The ALLG also hosted a Special COVID-19 Event focusing on practical experiences in Australia and New Zealand, chaired by Dr Robert Weinkove, A/Prof Zoe McQuilten and A/Prof Peter Mollee. ALLG Members received insightful presentations from guest speakers Prof Allen Cheng on the epidemiology of COVID-19, Dr Azhar Munas on his experience with COVID-19 in the laboratory, Dr Colin McArthur about the REMAP-CAP clinical trial and a pre-recorded interview with Prof Michael Joyner, Principal of the US National Convalescent Plasma Program.

The ALLG 2019 Research Report was also launched at the meeting. In the report, you can find full trial updates from the various disease-focused working parties, including Acute Leukaemia and MDS, CLL, CML/MPN, Laboratory Sciences, Lymphoma, Myeloma, Supportive Care, Transplantation & Cell Therapies Working Parties.

On the COVID-19 front, ALLG Member Relations Working Group Chair, Dr Robert Weinkove, was among a group of haematologists, oncologists and infectious disease physicians to publish interim guidance for haematology and oncology in the Medical Jounal of Australia (Weinkove et al, Med J Austr, 20 March 2020). The ALLG has been collaborating with over 14 charities converged by the Cancer Council of Australia to improve patient and physician communication at the emergence of the COVID-19 crisis. Please find the Australian and New Zealand companion information sheets to the MJA publication.

Contributed by Cara Makovic

Australasian Gastro-Intestinal Trials Group (AGITG)

Our COVID-19 response

As the COVID-19 pandemic evolves, we have also evolved the way we work. The impact of COVID-19 on our trials portfolio is reviewed on an ongoing basis to minimise any potential risk. We have created guidance documents to provide support for trial sites, and to serve as a guide for trial logistics and procedural adjustments to preserve the safety of participants.

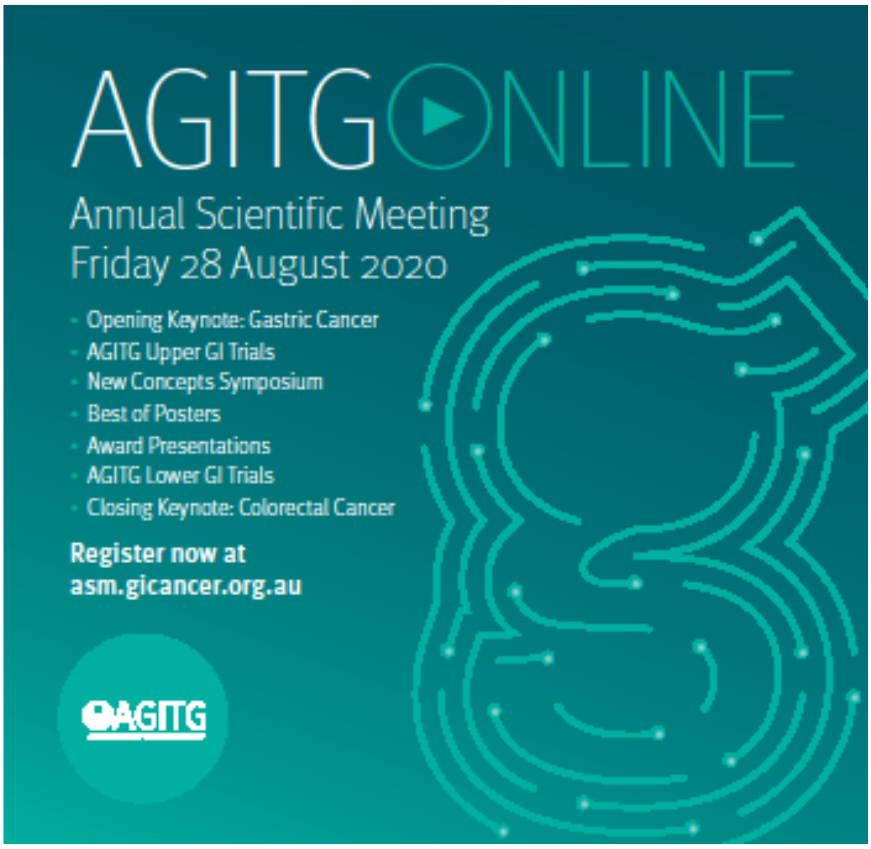
We have also taken action to support social distancing measures including cancelling face-to-face meetings and events throughout the first half of 2020, directing staff to work from home and postponing Gutsy Challenge fundraising events until 2021.

Dr Lorraine Chantrill welcomed as new Chair of the AGITG

On 15 May 2020, the AGITG welcomed Dr Lorraine Chantrill as the new Chair of the organisation. Dr Chantrill has also taken on the role of Chair of the Scientific Advisory Committee. Dr Chantrill is Head of Service of Medical Oncology at Illawarra Cancer Care Centre, Wollongong Hospital. She has served on the AGITG Upper GI Working Party since inception in 2011, has chaired the Working Party since August 2014, and was appointed to the Board of Directors of AGITG in August 2016.

Dr Chantrill says, "I hope to maintain and improve the good work of the AGITG while I'm Chair."

Dr Lorraine Chantrill



#AGITGonline: Our ASM will be virtual in 2020

We are pleased to announce the program for our first virtual ASM is now available. The 2020 Annual Scientific Meeting, convened by Professor Stephen Ackland, will feature keynote presentations from Professor Kohei Shitara and Dr Naureen Starling on current practice and controversies/developments in gastric and colorectal cancer respectively. View the ASM program here

The Idea Generation Workshop returns for 2020

New research ideas in early stage oesophageal cancer treatment will be discussed at the Idea Generation Workshop held in Sydney on Friday 6 November. Submissions of new ideas are welcome until Thursday 3 September – all you need is a one paragraph description of your idea to apply. Learn more about the Idea Generation Workshop.

Fight for the Frontline

During COVID-19, help our heroes on the frontline and support research by joining our community of fundraisers. Take on a fundraising activity at home or outdoors to let our frontline workers know we are still thinking of them through this difficult time, while raising funds for their vital work. Learn more about Fight for the Frontline.

Contributed by Jennifer Worgan

AGITG AUSTRALASIAN GASTRO-INTESTINAL TRIALS GROUP

SAVE THE DATE – CREST INTRODUCTION TO HEALTH ECONOMICS WORKSHOP

26TH OCTOBER, 2020

*** Please note that this is a save the date, and the conduct of the workshop as a face-to-face event will depend on social distancing measures at the time. The potential for online attendance will be considered pending demand.*
Registration for the workshop will open early September.

Title:	**Understanding health economics in cancer research**
Date:	9.30 am – 4.30 pm, Monday 26th October 2020
Venue:	Room D.2.20, Block D, Building 5, 1 Quay St, Ultimo, NSW.
Cost:	Registration is free to members of a Cancer Australia Co-operative Trials Group.

This workshop is for those working or interested in cancer research who may encounter health economics in research papers or policy documents, or who would like to consider how health economics may be incorporated into their own practice or research.

Workshop Program

The workshop will use a series of workshop-style seminars and exercises to provide theory and practical examples to cover:

⇒ An introduction to health economics and economic evaluation in research

⇒ Study design for economic evaluation in oncology research

⇒ Identifying, valuing and measuring outcomes

⇒ Identifying, valuing and measuring costs

⇒ Interpretation of results of economic evaluations

Participants at the workshop will receive a USB with course notes, including copies of the slides presented on the day, references used as examples throughout the workshop, and additional useful readings. Lunch and refreshments will be provided.

Participants will need to arrange their own travel to and from the workshop. CREST is unable to provide travel assistance for this workshop.

This workshop will be filmed for educational purposes and the focus will be on the presenters. If you prefer not to be filmed, please indicate when registering and we will seat you to the side of the room.

Workshop places are limited to 30 participants. Registration for the workshop will open early September. If you are interested, please send your name and trial group affiliation to:

Nancy Kim nancy.kim@chere.uts.edu.au

For more information about CREST, please visit our website: www.crest.uts.edu.au