Genomic Cancer
Clinical Trials Initiative

Genomic Cancer Clinical Trials Initiative

March 2023 Workshop Report

The Genomic Cancer Clinical Trials Initiative (GCCTI) is a grant funded by Cancer Australia and delivered in partnership between NHMRC Clinical Trials Centre and Zest.

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Introduction

The Genomic Cancer Clinical Trials Initiative (GCCTI) was established and funded by Cancer Australia in 2013. The GCCTI is a technical service that supports the national cancer cooperative trials groups (CCTGs) funded under Cancer Australia's *Support for Cancer Clinical Trials* program. The GCCTI aims to develop **mutation-specific/molecularly-targeted clinical trials concepts** and **grant applications involving cancers from more than one primary site and more than one CCTG**.

GCCTI is led by the National Health and Medical Research Council Clinical Trials Centre (NHMRC CTC) in partnership with Zest. Scientific technical expertise is provided by the NHMRC CTC, and project management, stakeholder engagement and communications expertise are provided by Zest.

The GCCTI project team held a one-day **Grant Development Workshop** on **Friday 31 March 2023** at the Chris O'Brien Lifehouse, Sydney; hybrid attendance was also made available via Zoom.

Purpose of the workshop

The GCCTI annual workshops aim to provide a forum for Australia's leading cancer researchers, CCTGs, and the GCCTI Scientific Steering Group (SSG) to discuss ideas and opportunities for studies and grants involving cancers from multiple primary sites and multiple CCTGs. This grant development workshop focused on strengthening grant applications for submissions in 2023 and beyond.

Objectives for workshop participants:

- Learn about current grant opportunities, guidelines, assessment criteria and recent changes
- Present synopses of grants for submission in 2023 for feedback from members and development groups
- Discuss and generate ideas for grants to submit beyond 2023, especially those including multiple cancer types and multiple CCTGs

The workshop program is included in the Appendix

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Overview of the GCCTI

The main aim of GCCTI is to help support the national cancer CCTGs by developing mutation-specific/molecularly-targeted clinical trials concepts and grant applications involving cancers from multiple primary sites and/or multiple CCTGs.

The scope and key deliverables of the GCCTI are to:

- Develop mutation-specific/molecularly-targeted clinical trial concepts and protocols that involve more than one cancer and more than one CCTG
- Submit grant applications for funding of these trials, including budget preparation
- Include quality of life and pharmaco-economic measures with input as appropriate from the Cancer Australia Technical Services for Quality of Life (CQUEST) and Health Economics (CREST)
- To host annual workshops welcoming all CCTGs and key stakeholders to identify potential targets for the development of mutation-specific cancer clinical trial protocols

The intended outcomes and benefits include:

- **Molecularly-focused networks** of researchers, clinicians and scientists
- **Increased capacity** to conduct genomic cancer clinical research
- **Strategies for managing challenges** associated with trials of targeted treatments
- **Structures to support the conduct** of trials that include multiple primary sites and multiple CCTGs

Continued engagement with Technical Services, including:

- Cancer Quality of Life Expert Service Team (CQUEST)
- Cancer Research Economics Support Team (CREST)
- Asia-Pacific Clinical Oncology Research Development Initiative (ACORD)

There are several ways that individuals can engage with GCCTI:

- Developing and submitting concepts/ideas to GCCTI
- Working with GCCTI and CCTGs to develop and design trial concepts
- Contributing to idea generation and prioritisation by attending GCCTI workshops and communicating with other CCTGs, researchers and the GCCTI project team
- Inputting into grant applications by joining GCCTI supported grant development teams

Grants update

Update on MRFF grants programs

A/Prof Ruth Griffiths (Director, Patients and Infrastructure, Health and Medical Research Office) provided an update on MRFF grants programs.

General points to note in applying for MRFF funding include:

- Read beyond the title and into each grant opportunity, including the objectives and outcomes, eligibility criteria and selection criteria
- Align to the Australian Medical Research and Innovation Priorities
- Meet the objective of the overarching MRFF initiative and the intention for the grant model
- Identify how the application will contribute to the MRFF measures of success (grants do not need to fulfill all measures, but should select those which are relevant)
- Include assessment criteria that are focused on outcomes

General considerations when applying

- How well does the application align with the:
    - Objectives and intended outcomes
    - Monitoring, evaluation and learning strategy – refer to the *MRFF Measures of Success*
    - Grant model

Clinical Trials Activity grant opportunity

The Clinical Trials Activity grant opportunity comprises four streams addressing:

- Rare cancers*, rare diseases*, unmet need†
  Stream 1: Conduct a clinical trial of one or more treatments and/or management-based interventions for rare cancers, rare diseases and/or unmet need
  Stream 2: Conduct an implementation science trial to determine the best strategies for reducing inappropriate antibiotic use in clinical settings

- Effective health interventions

  Stream 3: Conduct a clinical trial that reduces inequities in health outcomes by addressing the specific health and healthcare needs that are of priority for people in regional, rural and remote communities

  Stream 4: Conduct a clinical trial that assesses the comparative effectiveness of two or more health interventions to treat a specific clinical condition, to inform the decisions of policy makers, clinicians, and consumers regarding healthcare and to minimise the use of unnecessary, ineffective and harmful health interventions

*Rare cancer and rare disease are defined as life-threatening or chronically debilitating health conditions that affect fewer than 1 in 2000 people in the population
†Unmet medical need arises where individuals are living with a serious health condition, where there are limited satisfactory options for prevention, diagnosis or treatment to support improved health outcomes

This grant opportunity offers a maximum of $4 m per grant for up to 5 years. Key dates for the 2022 Clinical Trials Activity grant opportunity are as follows:

- **Opened** 14 December 2022
- **Minimum data due** 3 May 2023
- **Closing date** 28 June 2023

Update on NHMRC grants programs

Dr Wee-Ming Boon (Director, Clinical Trials and Cohort Studies Grants, NHMRC) provided an update on NHMRC grants programs, specifically Clinical Trials and Cohort Studies (CTCS). This scheme supports high-quality clinical trials and cohort studies that address important gaps in knowledge. It receives an annual allocation of ~$70 m and supports approximately 30 grants per year. In each grant round between 2019 and 2021, the funded rates were 5.4% (2019, n=570), 6.9% (2020, n=436), and 11.3% (2021, n=291). There were 243 applications in 2022 and outcomes are to be announced. The reason for the decreased number of applications is unknown. Other observations include:

- Requested budget ranges from $80 k to $12 m, but the total requested budget is decreasing ($1.01 b in 2019 to $575 m in 2022)
- The number of Chief Investigators (CIs) are increasing annually
- Higher funded rates for grants with female CI As compared with male

- Aboriginal and Torres Strait Islanders health applications do very well
- There is a 2-step peer review process. Each application is assessed by up to three independent experts, the top 30% of applications will then be reassessed by panel discussions and ranked. Funding is then granted accordingly
- Applicants will receive up to four sets of qualitative feedback (if the application reached the panel discussion stage). Those that do not will still receive up to three sets of qualitative feedback from their assessors

The CTCS is guided by three assessment areas, also known as category descriptors

- Significance: Tell a good story and provide evidence; it is encouraged to read NHMRC's Research Impact Position Statement
- Research quality: It is crucial that design details are included in the application e.g. sample size, blinding, trial design, inclusion/exclusion criteria, participant timeline. It is encouraged that applicants refer to the following:
    - SPIRIT Statement items (https://www.spirit-statement.org/spirit-statement)
    - STROBE reporting standard (https://www.strobe-statement.org)
- Team quality and capability: Applicants are encouraged to focus on the impact and outcomes that have been created, not only in peer-reviewed manuscripts, but how the work has contributed to policy and practice changes

The next round of CTCS grant applications opens on 28 June 2023.

Update on Cancer Australia grants

Jacqui Real (Director, Research and Investment, Evidence, Priority Initiatives Communications Branch, Cancer Australia) provided an update on the 2023 funding round of Cancer Australia's Priority-driven Collaborative Cancer Research Scheme (PdCCRS).

The PdCCRS is Cancer Australia's annual national research grants funding scheme, in which the agency joins with other government and non-government organisations to collaboratively fund national cancer research projects in areas of identified priority and thereby maximising value.

The structure of the 2023 funding round has largely remained the same:

- Standard project grants (established researchers, Category A), up to 3 years and $600,000; and Early Career Project Grants (Category B and C), up to 3 years post-qual (up to 1 year and up to $100,000) or 4–7 years post-qual (up to 2 years and up to $200,000)
- Research priorities in prevention; health services; cancer control, survivorship and outcomes; translational; and populations with poor and unwarranted variations in cancer outcomes
- Applications are submitted online, through Can-Grant (grants portal). The portal is aligned with NHMRC's SAPPHIRE portal, such that data from a completed NHMRC application can be downloaded and uploaded into Can-Grant

Key points to note:

- Ensure all possible research priorities that directly align with the proposal are selected. If a research priority is not selected, Cancer Australia are unable to recommend the application to the research partner/s and limits co-funding opportunities
- Upload evidence and report all consumer declarations/participation (from idea conception to dissemination of results)
- PdCCRS ideas grant round opened on 30 March 2023 and will close on 31 May 2023; Clinical Trials and Cohort Studies grant closes on 23 August 2023 (NHMRC) and 30 August 2023 (PdCCRS). The results will be announced in December 2023 and April 2024, respectively

Grant review and peer input

GeneScreen 5FU – Genotype-guided personalised fluoropyrimidine dosing: feasibility and implementation

Professor Steve Ackland (Medical Oncologist) presented an update on a proposal for GeneScreen. This proposal was also presented at the previous Ideas Generation Workshop in 2022 and was submitted to the MRFF (Genomic Health Futures Mission Grant) and Cancer Institute of NSW (Accelerated Research Implementation Grant). The grant proposes to demonstrate the cost effectiveness of DPYD genotyping in patients who may be prescribed fluoropyrimidine (FP).

In the last 18 months, a feasibility study involving over 100 participants, over 4 sites, was run. It involved obtaining a blood sample from the participant and performing DPYD genotyping (by real-time polymerase chain reaction, RT-PCR). The primary endpoint is genotype turn-around time (aiming for 7-day turn around), DPYD variant prevalence, and toxicity and dose outcomes (secondary).

The outcomes from the feasibility study include:

- Of the 101 participants recruited, 15 have been found to carry DPYD variants
- Turn-around time of 6.5 days (one RT-PCR run in the facility per week, if there was more demand, the facility is equipped to run two RT-PCRs per week, which would improve turn-around time)
- Grade 3/4 toxicity experienced in 7 of 15, and one participant died due to toxicity
- Three manuscripts accepted, several posters and presentations
- Small pilot study grant

The next interventional study proposed aims to recruit and genotype 2000 participants in NSW (possibility to extend to Australia-wide at a later stage). Participants are no longer required to have previous FP treatment and the procedure and primary endpoint are consistent with the feasibility study. A dose recommendation will be returned to the participant's clinician according to the Dutch guidelines. The participant's optimal dose will be established over the next cycles depending on the toxicity experienced.

Stereotactic ablative radiotherapy for oligometastatic disease following initial systemic therapy

A/Prof Eric Hau (Radiation Oncologist) presented a seamless phase 2/3 study of radiation for induced/repeat oligo-persistent disease following initial systemic immunotherapy; a proposal in development with A/Prof Chee Lee and A/Prof Mark Pinkham. This was also presented at the previous Grant Development Workshop in May 2022.

Checkpoint inhibitors are used successfully in many locally advanced/metastatic cancers, however a complete response is rarely achieved. Persistent cancer cells are a major reason for treatment failure, often occurring in sites of previous known disease. The persistence of a disease may also continue to evolve and result in further treatment resistance and distant seeding. The oligometastatic state refers to a state where there is limited metastatic disease but the full capabilities of widespread dissemination have not developed.

In palliative settings, local radiation has traditionally been given for symptom-control but is not known to improve survival. Pre-clinical and clinical evidence suggests radiotherapy and immunotherapy may be synergistic. Radiotherapy is known to induce cell surface markers which in turn activate the immune system and increase antigen release. Stereotactic radiation potentially removes clones which evolve into resistant cells and it is thought that earlier intervention with radiation may improve outcomes.

There are a large number of randomised phase 3 trials across various tumour types that are asking whether there is any benefit of stereotactic radiotherapy in the setting of oligometastatic disease (in addition to standard of care systemic therapy). However, the timing of adding stereotactic radiation to systemic therapy has varied and the optimal timing to implement stereotactic radiation is yet to be established, for example, in the oligo-persistent or oligo-progressive setting.

The proposed study aims to directly compare the addition of stereotactic radiotherapy in the oligo-persistent vs oligo-progressive setting and hypothesises that earlier intervention with stereotactic radiotherapy will be beneficial.

The proposed study is a seamless phase 2/3 randomised controlled trial, randomised treatment vs control for patients with locally advanced or Stage 4 non-small cell lung cancer, melanoma, renal cell cancers who have recently started checkpoint inhibitor immunotherapy

as a single agent or combination immunotherapy or chemotherapy/immunotherapy combination.

- Participants will be randomised to stereotactic radiation for oligo-residual disease or continue systemic therapy and receive stereotactic radiation at oligo-progressive disease
- The treatment would involve stereotactic radiation delivered as 1–5 fractions depending on anatomic site (if stereotactic radiation therapy is not feasible, fractionated radiation therapy of 10–15 fractions also permitted)
- Endpoints include progression-free survival (first progression; primary endpoint in the phase 2 study and secondary endpoint in the phase 3 study), overall survival (primary endpoint in the phase 3 study and secondary endpoint in the phase 2 study), feasibility (phase 2 study), local control, patterns of failure, second progression-free survival, frequency and severity of adverse events, time until change in systemic therapy, quality of life (QLQ C-30) and fear of cancer recurrence
- Secondary outcomes also include a health economics evaluation
- Tertiary outcomes include determining prognostic and/or predictive factors, including results of baseline ctDNA, and defects in homologous combination DNA repair
- The proposed sample size for the phase 2 study will be 120 participants; this allows approximately 20 patients in each histological tumour cohort; if at least 14 of a particular histological tumour cohort have progressed within 12 months, that cohort would not proceed to the phase 3 study
- The proposed sample size for the phase 3 study will be 520 participants

Intraperitoneal bevacizumab for recurrent, malignant ascites (REZOLV3R)

A/Prof Katrin Sjoquist (Medical Oncologist) presented an update on the REZOLV3R concept, which follows the completed REZOLVE trial. This proposal involves input from various CCTGs including, Cancer Symptom Trials (CST), Australasian Gastro-Intestinal Trials Group (AGITG), and Australia New Zealand Gynaecological Oncology Group (ANZGOG). It was also presented at the previous Grant Development Workshop in May 2022 and was submitted as an NHMRC CTCS application in August 2022. The background is that:

- Malignant ascites is a common and important problem in a variety of cancer types, including ovarian cancers

- There is no treatment approved in Australia for malignant ascites
- Vascular endothelial growth factor (VEGF) plays a pivotal role in malignant ascites and bevacizumab binds to all major isoforms of human VEGF-A and prevents VEGF from interacting with its receptors and inhibits activation of downstream signaling pathways

The single-arm, phase 2 REZOLVE trial tested intraperitoneal bevacizumab (IP-bev) for recurrent, symptomatic ascites in patients with chemotherapy-resistant, epithelial ovarian cancer with results published in 2021. REZOLVE demonstrated that the paracentesis-free interval after the first dose of IP-bev was 4.3 times as long as it was before the first dose of IP-bev. The study concluded that IP-bev was safe, active, and warrants further study as a palliative intervention for recurrent ascites in chemotherapy-resistant, epithelial ovarian cancer.

REZOLV3R is a proposed randomised (1:1), double-blind, multicentre, phase 3 trial of palliative IP-bev following therapeutic ascitic drainage for recurrent, malignant ascites in patients with chemotherapy-resistant solid tumours. It hypothesises that IP-bev will meaningfully prolong the time between required paracentesis for symptomatic ascites in malignant cancer to improve patient quality of life and reduce healthcare utilisation costs.

Stratification factors include: primary tumour site, performance status, prior bevacizumab use, and study site.

- The primary endpoint is post-treatment paracentesis-free survival time: days from baseline paracentesis to next paracentesis or death
- The proposed population includes symptomatic patients with recurrent malignant ascites suitable for paracentesis and a paracentesis-free interval of 28 days or less. Temporary or indwelling catheters for paracentesis are allowed. Prior IV-bev is allowed provided ascites did not progress or recur while receiving this
- Study assessments include i) clinical assessment and patient reported outcomes (PROs) at baseline, before on-study paracentesis; ii) clinical assessment and PROs, and adverse events at each subsequence paracentesis, or every 4 weeks, if no further paracentesis is required; biospecimens (blood and ascites) at each paracentesis plus archival tissue for translational research
- All participants will receive therapeutic paracentesis according to local guidelines. The proposed intervention involves intraperitoneal instillation of 100 mL saline with 400 mg

bevacizumab over 30 mins, followed by 400 mL saline over 30–60 mins (exactly as was done in the phase 2 trial). The proposed control treatment is identical but without the addition of bevacizumab

- Participants requiring a subsequent paracentesis may be treated with IP bevacizumab at the discretion of the participant and clinician
- The proposed sample size is 200 participants. This provides 90% power with 2-sided type 1 error rate of 5% if the true median post-treatment paracentesis-free survival time of 48 days in the experimental group vs 28 days in the control group, with over-accrual of 20% to account for missing data

Denosumab And Immunotherapy in advanced Solid cancers (DAIS)

Angelina Tjokrowidjaja (Medical Oncologist and GCCTI Research Fellow) presented an open-label, randomised phase 2/3 basket trial to evaluate the combination of denosumab with immunotherapy in advanced solid malignancies. This proposal was also presented at the previous Grant Development Workshop in May 2022 and was submitted as an NHMRC CTCS application in August 2022. The background is that:

- Immune checkpoint inhibition (ICI) has improved survival outcomes in a range of advanced solid malignancies compared with other treatments such as chemotherapy. However, only 13–40% derive durable benefit on immunotherapy monotherapy
- Doublet ICI is associated with increased response and benefit, but is costly and is associated with significant toxicity
- ICI treatment has poorer response and survival outcomes in the subset of patients with solid malignancies and bone cancer compared with those without bone metastases
- There is still an unmet need to improve the benefit of ICI without increasing financial cost or toxicity in patients with advanced cancer, especially with bone metastases

Denosumab, a RANK ligand (RANKL) inhibitor, is widely used in osteoporosis and is also used to delay skeletal-related events in people with bone metastasis from prostate, breast and other cancers. In addition, denosumab has immunomodulatory effects and pre-clinical data shows synergistic effects with combination RANKL inhibitor and ICI treatment.

The hypothesis is that the addition of denosumab to ICI provides i) a quantitative improvement to overall progression-free survival and objective response rate; ii) no increase in grade 3/4 adverse events or treatment discontinuation; and iii) an increase in CD4+ and CD8+ T-cells as markers of immune activity.

The proposed design is a randomised (2:1), controlled, basket trial of combining denosumab with a Pharmaceutical Benefits Scheme (PBS)-subsidised ICI in advanced cancers with bone metastases.

- The primary endpoint is progression-free survival (investigator assessed). Secondary endpoints include progression-free survival (6 and 12 months), objective response rate and disease control rate, time to objective tumour response, frequency and severity of grade 3/4 adverse events, time to first skeletal-related adverse event and treatment delays and discontinuations due to toxicity
- The proposed treatment groups are:
    - Experimental – ICI monotherapy according to standard schedule plus denosumab 120 mg, every 3–4 weeks until week 24, then every 6–8 weeks until 1 year
    - Control – ICI monotherapy according to standard schedule without denosumab
- Participants will be randomised 2:1 with a target sample size of 300 participants to provide 80% power with a 1-sided type 1 error rate of 0.05, one interim futility analysis will be applied (n=150) and if the threshold is not met for futility, the study will transition to a second stage (n=150)

Ventilation Imaging to reduce Toxicity for Lung cancer radiation therapy patients (VITaL)

Professor Paul Keall (NHMRC Leadership Fellow) presented a proposal that uses ventilation imaging to help maintain the quality of life of patients with stage 2/3 non-small cell lung cancer (NSCLC).

Radiation is a commonly used therapy in patients with lung cancer. It involves balancing a curative dose while sparing healthy organs, particularly the lungs. However, radiation-induced lung injury is a common adverse event of radiation therapy. Ventilation imaging

involves using computed tomography (CT) lung images to plan treatment to spare healthy lung tissue from radiation-induced lung injury.

The hypothesis is that patients with a health lung-sparing treatment plan (interventional arm) will i) maintain their quality of life more than patients receiving standard care; ii) show reduced clinician-measured treatment side effects and superior survival and local control.

The proposed design is a double-blind, randomised, controlled trial:

- The trial will measure quality of life, toxicity, survival, and local control
- The proposed treatment groups are:
    - Interventional arm – Treat patient using health lung-sparing plan
    - Control – Treat patient using standard treatment plan
- It is anticipated 160 patients will be recruited over three years from eight centres

Addition of stereotactic radiosurgery to molecular targeted therapies in driver mutation positive non-small cell lung cancer with persistent brain metastases (OUTRUN-P)

Dr Yu Yang Soon (Radiation Oncologist) presented a trial concept that uses stereotactic radiosurgery in addition to molecular targeted therapies to improve survival in patients with driver mutation positive non-small cell lung cancer with persistent brain metastases.

In general, past phase 3 trials comparing systemic treatments in patients with NSCLC have excluded patients with brain metastases. Further, recent American Society of Clinical Oncology (ASCO) - Society for Neuro-Oncology (SNO) - American Society for Radiation Oncology (ASTRO) guidelines recommend that local therapies may be deferred for those with asymptomatic brain metastases and on central nervous system (CNS) active systemic therapies; yet, the strength of the recommendation was considered weak.

In another retrospective study, a significantly higher incidence of progression at one year was found in patients with partial response or stable brain metastases after a median duration of 2 months of osimertinib, compared to those with complete response.

The hypothesis is that stereotactic radiosurgery in combination with tyrosine kinase inhibitors (TKIs, e.g. osimertinib, alectinib, brigatinib, ceritinib) will improve intracranial progression-

free survival at 12 months compared with continuing TKIs followed by local therapies for patients with persistent brain metastases after three months of TKIs.

The proposed design is a randomised Phase 2 trial.

- Eligibility criteria are similar to OUTRUN and LUOSICNS, with the exception of having 3 months of TKIs
- To primary objective of this study is to determine the efficacy and safety of adding stereotactic radiosurgery to continuing TKIs with continuing TKIs followed by local therapies at progression in participants with driver mutation-positive NSCLC after three months of TKIs and up to 10 lesions at the time of randomisation
- The primary outcome is intracranial progression-free survival at 12 months. Secondary outcomes include intracranial progression-free survival, time to local brain failure, time to distant brain failure, time to salvage local cranial therapies, progression-free survival, overall survival, adverse events and health-related quality of life
- The proposed treatment groups are:
    - Interventional arm – Continue TKIs with the addition of stereotactic radiosurgery, followed by local therapies at progression
    - Control – Continue TKIs alone, followed by local therapies at progression
- Participants will be randomised 1:1 with a target sample size of 70 participants. This provides 80% power with 2-sided type 1 error rate of 0.05, with three years of accrual and one year of follow-up
- There is potential for this trial concept to be applied in other cancer groups, including, epidermal growth factor receptor (EGFR) mutant NSCLC, programmed death-ligand 1 (PD-L1) positive NSCLC, and human epidermal growth factor receptor-2 (HER2) positive breast cancer

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Workshop evaluation

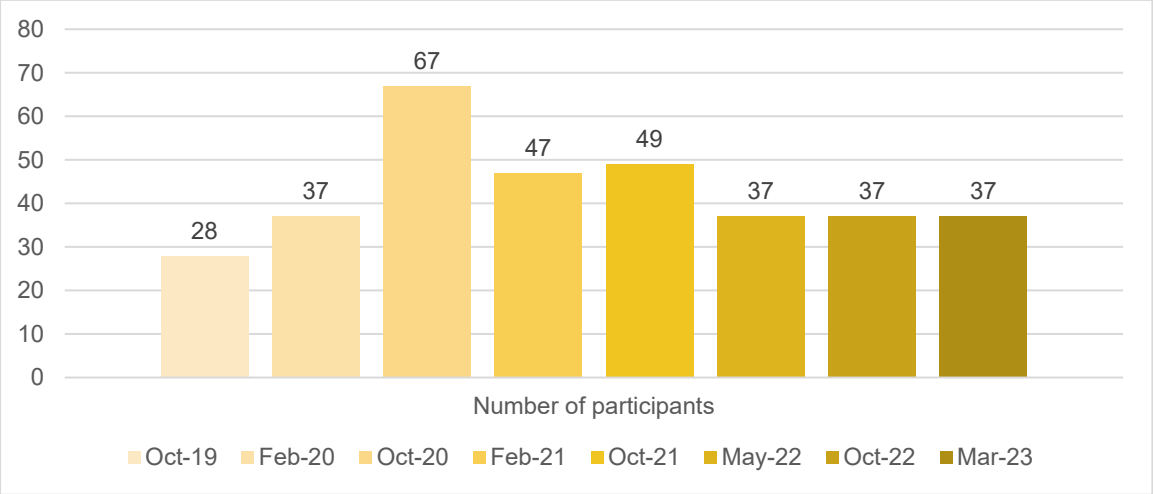
Introduction

The GCCTI is committed to continuous quality improvement and values workshop participants' feedback to help identify opportunities to improve future workshops. Workshop participants completed an online survey to provide feedback.

Participation and survey response rate

Thirty seven participants attended the GCCTI March 2023 workshop; 13 participants (35%) attended in-person and 24 participants (65%) attended virtually.

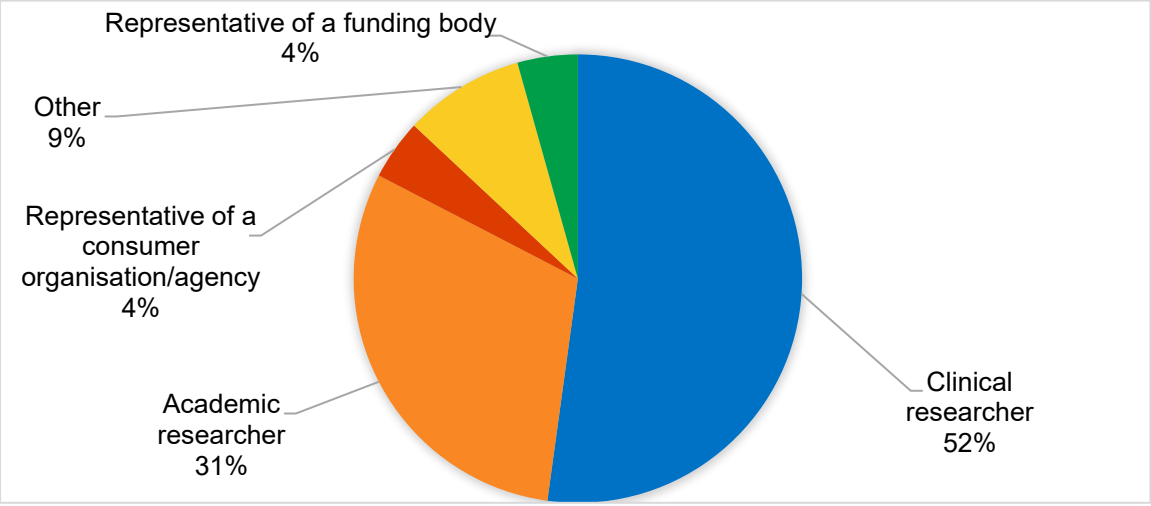
Figure 1: Number of participants at GCCTI workshops (frequency)



Eighteen of the 37 participants who attended the workshop completed the survey (a 49% response rate), an increase in the response rate from the previous workshop, which was 32%.

The majority of survey respondents identified as clinical researchers (67%), followed by academic researchers (39%).

Figure 2: Participant roles (frequency and proportion)



Organisations/groups in attendance

Participants from organisations/groups across Australia attended, including one international participant.

- Blacktown Hospital, NSW
- Cancer Australia
- Concord Hospital, NSW
- Commonwealth Department of Health
- EHE Rare Cancer Foundation Australia
- Fiona Stanley Hospital, WA
- Monash Health, VIC
- Murdoch University,
- NHMRC
- NHMRC Clinical Trials Centre, NSW
- Peter MacCallum Cancer Centre, VIC
- St Vincent's Hospital, NSW
- The University of Newcastle, NSW
- The University of Sydney, NSW
- University of Technology Sydney (UTS), NSW
- Westmead Institute for Medical Research (WIMR)
- Cancer service – CQUEST
- Cooperative Clinical Trials Groups (CCTGs)
    1. AGITG
    2. ANZCHOG
    3. ANZGOG
    4. ANZSA
    5. ANZUP
    6. BCT
    7. COGNO
    8. MASC
    9. PaCCSC & CST
    10. PC4
    11. PoCoG
    12. TOGA
    13. TROG

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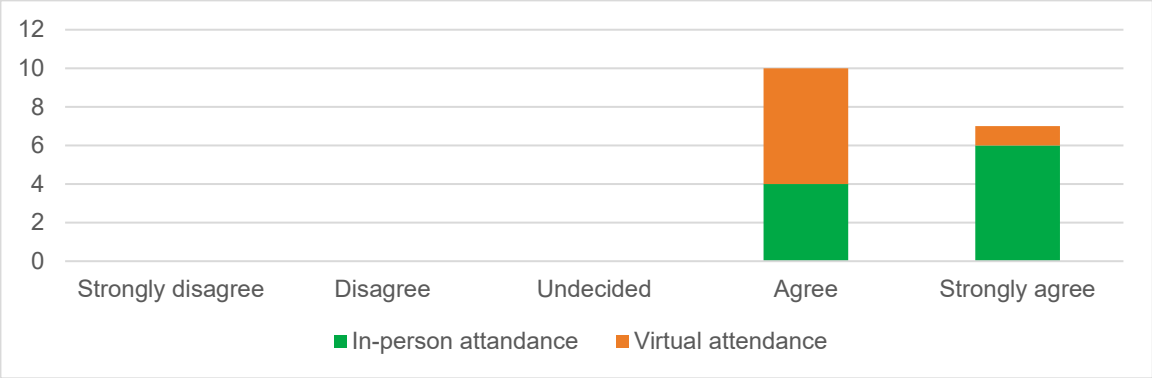
Understanding the workshop's aim and purpose

Figure 3: Number of participants that understood the aim and purpose of the workshop

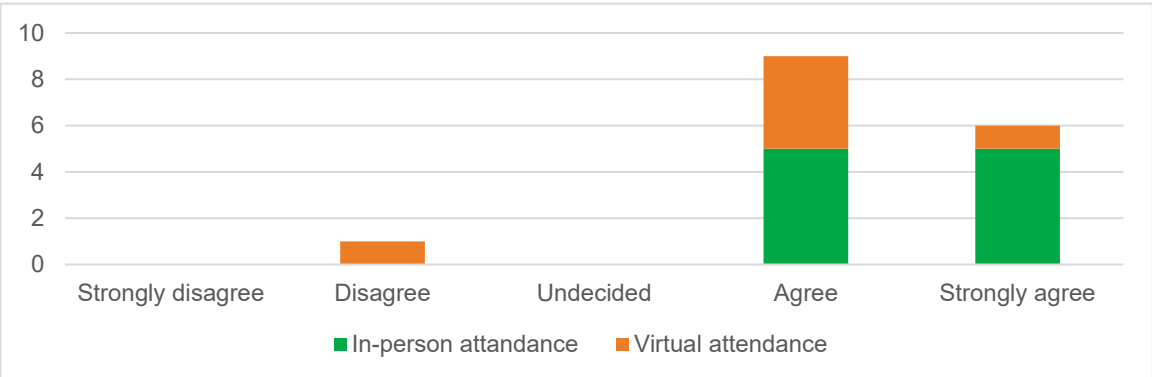


100% of respondents indicated that they had a clear understanding of the aims and purpose of the workshop. Respondents noted:

"Clearly enunciated in meeting communications and at the start of the day." – Virtual attendance

Usefulness and relevance of the presentations

Figure 4: Number of participants that found the content useful and relevant



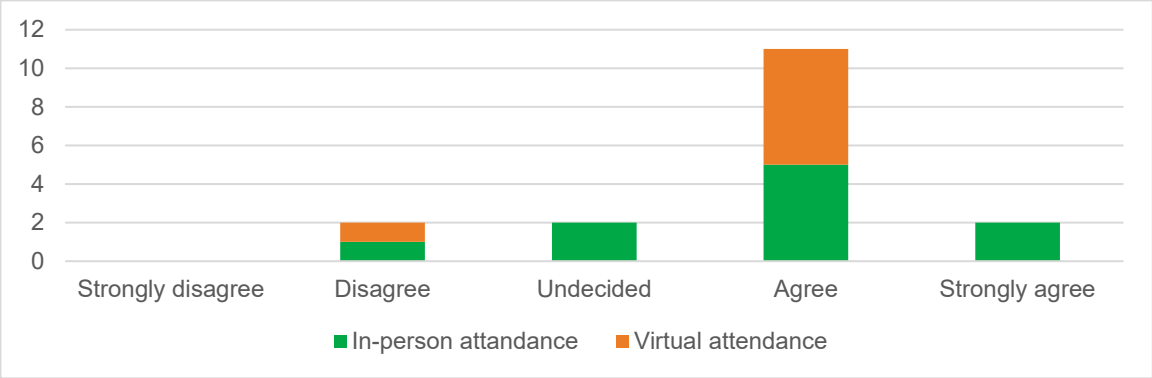
94% of respondents indicated that they found the content of the workshop presentations useful and relevant. Respondents noted:

"Refreshing to see the work of peers with similar interest." – In-person attendance

"Grants presentations relevant. Always interesting to hear what adult cancer researchers are working on but as usual very difficult to work childhood cancer participants could fit into the proposed studies due to diagnoses, clinical problems etc. Always good to think about PROs." – Virtual attendance

Organisation of workshop

Figure 5: Number of participants that found the hybrid format to work well



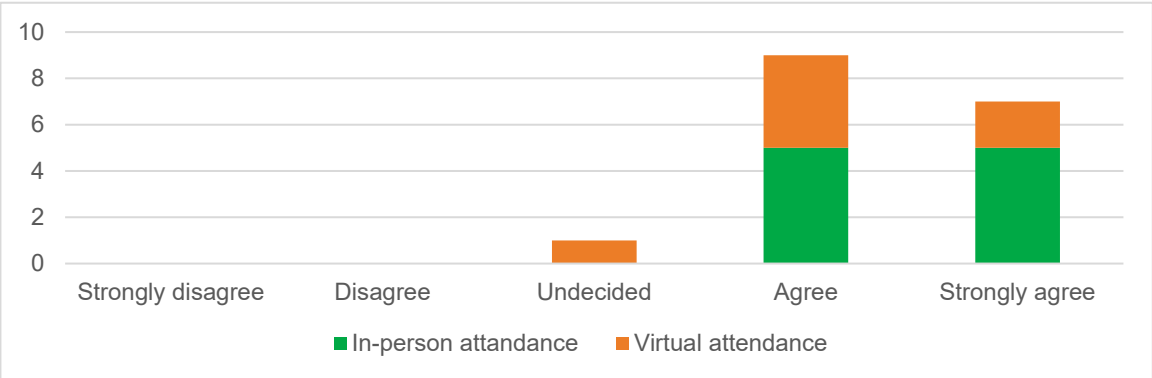
88% of respondents indicated that the hybrid format worked well. Respondents noted:

"Good to use technology to facilitate broader attendance, but more engagement face to face" – In-person attendance

"I prefer all face to face primarily for networking and had really good chats with others that attended face to face" – In-person attendance

"Like the choice for hybrid. Tech issues with volume of sound and interference inevitable however should not stop this option" – Virtual attendance

Figure 6: Number of participants that found the workshop well organised



94% of respondents indicated that the workshop was well organised. One respondent noted:

"Would have been good to get concepts a bit earlier. As a non-expert, I would have liked more time to understand the different areas" – In-person attendance

Topics/aspects most interesting/useful

Participants were asked to comment on which workshop topics and aspects they found most interesting. Participants found all elements of the workshop interesting and useful, including:

- Grants Update (50%)
- Grant review and peer input for submissions (56%)
- Grant concepts (33%)

Respondents noted:

"Great to have input from those who are on the assessment end of grants about what features a successful application will have. Also great to have multiple research specialties present to give feedback – always eye opening to hear questions I would never have thought of."

"Appreciate the speakers from the various funding bodies."

"The combination of presentations from granting bodies, as well as individual grant concepts, worked well."

Additional comments/suggestions to enhance future workshops

Participants were asked for suggestions to further improve workshops; the following suggestions were provided:

Organisation

- Earlier invitation
- Clearer allocation of time
- E-listing of attendees circulated with agenda
- Microphone feedback

Workshop format

- Structure/template for concept presentations
- Reviewers such as the mock grant review panel

Topics

- More proposals
- Successful grant applicants to share their story
- Grant review panel chairs: what sinks/swims a grant quickly

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Appendix: Workshop agenda
Genomic Cancer Clinical Trials Initiative
1-day Grant Development Workshop Program

Venue Education Room, Chris O'Brien Lifehouse and via Zoom

Date Friday 31 March 2023

Time 9.30 am – 4.00 pm

Purpose To strengthen grants applications for submission in 2023 and beyond

Time	Session	Presenter
9:30–10:00 am	*Log in, morning tea and registration*	
10:00–10:15 am	**Welcome and introductions**	*Martin Stockler*
	Overview of GCCTI and achievements to date	*Martin Stockler*
10:15–10:45 am	**Grants Update: what's new and helpful for grant-writers**	
	• MRFF – Cancer Clinical Trial Grant Opportunities • NHMRC – Clinical Trials and Cohort Studies	*Ruth Griffiths* *Wee-Ming Boon*
10:45–11:00 am	**Grant review:** DPYD pharmacogenomics and Fluoropyrimidine dosing	*Stephen Ackland*
11:00–1:00 pm	*Lunch/Break*	
1:00–1:15 pm	**Grants update:** PdCCRs – Updates from Cancer Australia	*Jacqui Real*
1:15–3:45 pm	**Grant review and peer input for 2023 submissions**	*Group Discussion*
	Attendees present grant applications proposed for submission in 2023 to receive feedback from expert peers reflecting NHMRC criteria and processes.	
	• Stereotactic ablative radiotherapy therapy for oligometastatic disease following initial systemic therapy: A randomised adaptive seamless phase 2/3 study • Intraperitoneal anti-VEGF for recurrent, malignant ascites • Randomised trial of denosumab with immune checkpoint inhibitors • A randomised controlled trial investigating Ventilation Imaging to reduce Toxicity for Lung cancer radiation therapy patients (VITaL) • Stereotactic radiation for brain metastasis • Late breaking grants	*Eric Hau* *Katrin Sjoquist* *Angelina Tjokrowidjaja* *Paul Keall* *Yu Yang Soon* *TBC*
3:45–4:00 pm	**Wrap-up and close**	*Martin Stockler*