Genomic Cancer
Clinical Trials Initiative

Genomic Cancer Clinical Trials Initiative

May 2022 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 (CTGs) 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 CTG**.

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 virtual **grant development workshop** on **Friday 6 May 2022.**

Purpose of the workshop

The GCCTI annual workshops aim to provide a forum for Australia's leading cancer researchers, CTGs, and the GCCTI Scientific Steering Group (SSG) to discuss ideas and opportunities for studies and grants involving cancers from multiple primary sites and multiple CTGs. This grant development workshop focused on strengthening grant applications for submissions in 2022 and beyond.

Objectives for workshop participants:

- Learn about current grant opportunities, guidelines, assessment criteria and recent changes
- Present synopses of grants you plan to submit in 2022 for feedback from members and development groups
- Discuss and generate ideas for grants to submit beyond 2022, especially those including multiple cancer types and multiple CTGs

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 CTGs by developing mutation-specific/molecularly-targeted clinical trials concepts and grant applications involving cancers from multiple primary sites and/or multiple CTGs.

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 CTG
- 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 CTGs 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 CTGs

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 CTGs to develop and design trial concepts
- Contributing to idea generation and prioritisation by attending GCCTI workshops and communicating with other CTGs, 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 Webster (Director, Patients and Infrastructure, Health and Medical Research Office) provided an update on MRFF grants programs.

The second 10-year MRFF plan includes $6.3 billion of funding for medical research over 10 years (2022–23 to 2031–32). In addition to enhancing and expanding existing MRFF initiatives, the recent update also allocated funds for a new MRFF initiative to support early to mid-career researchers to enable them to work on greatest health challenges.

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
- 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

Recent news and activities to look out for:

- The first 10-year MRFF plan focused on clinical trials addressing rare cancers, rare diseases and unmet needs, and Australian participation in international clinical trials. Through the second 10-year MRFF plan, a new stream (effective health interventions) enables funding in research projects focused on any disease or condition that meets the objective specified in each grant opportunity
- The 2021 clinical trials initiative closes on 6 July 2022
- The 2022 International clinical trial collaborations grant closes on 3 August 2022 (round 1) and 22 February 2023 (round 2) – one of the key aims is to provide Australian patients with access to new treatments, especially for rare conditions where it may not be feasible to run an entire trial in Australia (note: this grant will not fund the Australian

component of international clinical trials, however, grant funding cannot be used to support overseas sites. Trials may originate either in Australia or overseas)

- The 2021 early to mid-career researchers grants close on 13 July 2022. The grant has several streams which allow for early stage, small-scale research projects to larger, industry collaboration and translational opportunities
- Continue to visit the MRFF website for new initiatives as they are released
- To keep connected:
    - Subscribe to MRFF news here
    - Nominate for an MRFF Grant Assessment committee here
    - Register for MRFF grant opportunities here
    - Follow Health Twitter for MRFF updates (@healthgovau #MRFF)

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. This scheme receives an annual allocation of approximately 7.5% of the Medical Research Endowment Account (MREA), which is awarded across approximately 30 grants per round; in 2019 and 2020. In 2019 and 2020, the funded rates were 5.4% and 6.9%, respectively.

- There is intersecting eligibility criteria across the grant schemes and Clinical Trials and Cohort Studies may receive funding through other NHMRC schemes, for example, Partnership Projects
- The number of Chief Investigators (CIs) are increasing annually
- Higher funded rates for grants with female CIAs compared with male
- Aboriginal and Torres Strait Islanders health applications do very well
- In September and October, each application is assessed by up to three independent experts; the top 30% of applications will then be discussed and reassessed by panels of 10 to 15 members in February the following year
- 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

Characteristics of a strong application:

- The application should be tailored to the scheme, for example, an Ideas Grant vs Clinical Trials and Cohort Studies will have different assessment criteria and should be targeted as such
- Clearly addressed all assessment criteria and speaks to each point of the scoring criteria
- Well written, concise and easy-to-read application that is understood by a broad expertise panel
- Contains no errors (in spelling or information)
- The application is written specifically for the grant rather than being repurposed from another scheme
- Follows the instructions
- Does not contain too many acronyms or too much technical or assumed knowledge

Characteristics of a strong Clinical Trials and Cohort Studies grant application:

- Provide strong evidence for the 'why' of the application, e.g. systematic review?
- Addresses the assessment criteria and category descriptors well
- Do refer to the following:
    - SPIRIT Statement items (https://www.spirit-statement.org/spirit-statement)
    - STROBE reporting standard (https://www.strobe-statement.org)
    - Indigenous Research Excellence Criteria
- Appropriate and clearly thought-out budget
- Addresses consumers and end-user involvement and benefits
- Appropriate governance and ethics
- Contains risk management and implementation strategies
- Capacity and capability building: early and mid career researchers

Update on Cancer Australia grants

Dr Gayle Jones (Assistant Director, National Research and Data, Cancer Australia) provided an update on the status of Cancer Australia's annual research grants program.

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.

In addition, the PdCCRS international (PdCCRSi), established in 2018, is a collaborative grants program partnering international funders of cancer research to support Australia-based cancer research investigators. It uses a merit and peer review process to identify applications that address the priorities common to both Cancer Australia and the international funder. PdCCRSi is complementary to PdCCRS.

Updates to the 2022 round:

- Refreshed strategic evidence-based research priorities for the 2022–24 rounds
- Ovarian Cancer Research Foundation has become a new funding partner in 2022

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
- PdCCRS ideas grant closed on 11 May 2022 and the Clinical Trials and Cohort Studies grant closes on 1 September 2022. The results will be announced in December 2022 and March/April 2023, respectively

Grant review and peer input

This session included three grant presentations.

Randomised trial of denosumab and immunotherapy in advanced solid cancers

Angelina Tjokrowidjaja (Medical Oncologist and GCCTI Research Fellow) presented an open-label, randomised phase 2 basket trial to evaluate the activity of denosumab and immunotherapy in advanced cancers.

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. Further, treatment with ICI has poorer response and survival outcomes in the subset of patients with solid malignancies and bone cancer compared with those without bone metastases. Therefore, 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 combination of denosumab and ICI provides a biologically rational immunomodulatory strategy to improve the effects of ICI in a safe, effective and relatively cheap way for patients with a range of advanced solid cancers.

The proposed design is a randomised, controlled, basket trial of combining denosumab with a Pharmaceutical Benefits Scheme (PBS)-subsidised ICI in advanced cancers including non-small cell lung cancer, melanoma, urothelial cancer, clear-cell renal cell cancer, head and neck cancers and MSI-high colorectal cancer.

- The primary endpoint is progression-free survival at 12 months. Secondary endpoints include progression-free survival, overall survival, objective tumour response rate, disease control rate, time to objective tumour response, adverse events, treatment delays, discontinuations and patient reported outcomes
- The proposed treatment groups are:
    - Experimental – ICI monotherapy according to standard schedule plus denosumab 120 mg, every 4–6 weeks, together with ICI for up to one year
    - Control – ICI monotherapy according to standard schedule without denosumab
- Participants will be randomised 2:1 with a target sample size of 300 participants recruited over 2 years with an additional follow-up of 12 months to provide 80% power with a 2-sided type 1 error rate of 0.05, assuming 5% over-accrual, one interim analysis and true progression free survival rates at 1 year of 30% in the control group vs 45% in the experimental group

Comments and suggestions included:

- **Facilitators for participation:** Consider regional populations and use of tele-trials
- **Comparator:** zoledronic acid could be used as an active comparator to control for effects on bone and bone marrow
    - Any participant developing hypercalcaemia during the trial would be able to access bisphosphonates/denosumab as per standard of care
- **Denosumab availability through compassionate access program:** investigators should be provided with clear instructions on how they could access denosumab through the compassionate access program to assist in recruitment for the study
- **Follow-up and imaging within standard of care**
- **Patient reported outcomes:** EORTC QLQ-C30 a good choice as patient reported outcome measure for quality of life
- **Addressing checklists:** address SPIRIT PRO and SPIRIT Path checklists
- **Translational research:** bone turnover markers in blood and urine could be assessed as part of the translational component of the study

Intraperitoneal anti-VEGF for recurrent, malignant ascites

Katherine Francis (Medical Oncologist) presented an update on the REZOLV3R concept, which follows the completed REZOLVE trial. The background is that:

- Malignant ascites is a common and important problem in ovarian and other 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, controlled, multicentre, phase 3 trial of IP-bev following therapeutic ascitic drainage for recurrent, malignant ascites in patients with chemotherapy-resistant solid tumours and a paracentesis-free interval of 28 days or less. Patients with indwelling drainage catheters, concurrent systemic therapy and/or prior treatment with intravenous bevacizumab are eligible.

Stratification factors include: primary tumour site, performance status, prior bevacizumab use, time since prior paracentesis and use of concurrent systemic anticancer therapy.

- The primary endpoint is paracentesis-free interval: days from baseline paracentesis to next paracentesis
- The proposed experimental treatment is intraperitoneal instillation of 100 mL saline with bevacizumab 5 mg/kg, 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

- During the development of REZOLV3R, bevacizumab was withdrawn from the Australian market by Roche after the Amgen biosimilar MVASI was given an unrestricted approval on the PBS for intravenous use
- Study assessments include i) prior to drainage – body weight, abdominal girth and health-related quality of life (HRQL) and ii) subsequent to drainage – adverse events and HRQL every 3–4 weeks
- The proposed sample size is 200 participants. This provides 80% power with 2-sided type 1 error rate of 5% if the true proportion of participants with a doubling of their paracentesis-free interval was 20% in the control group vs 40% in the experimental group, with over-accrual of 20% to account for missing data
- The proposed accrual time is 2 years with an additional 3 months for follow-up

Aspects currently for discussion include:

- **Blinding** of treatment allocation is proposed for the first intraperitoneal instillation. All participants are able to access bevacizumab for subsequent therapeutic taps
- **Sample size** is ambitious, and would make this one of the largest trials of its kind, but there is no restriction on cancer type
- **Additional saline in both groups:** the additional 400 mL saline is intended to maximise dispersion throughout the peritoneal cavity and did not pose any problems in the phase 2 REZOLVE trial. Consideration could be given to using a smaller volume, or to allowing drainage before removing/clamping the catheter
- **Translational correlative studies** could include collections of ascitic fluid before and after intraperitoneal instillation to assess concentrations of study drug and/or other biomarkers
- **Possible paediatric participation** should be discussed with ANZCHOG
- **Health-economic considerations** are likely to be important and a health economic evaluation would be worthy of incorporation

Stereotactic radiation as consolidation following immunotherapy

Eric Hau (Radiation Oncologist) presented a prospective phase 2/3 study of radiation for induced/repeat oligo-persistent disease following initial systemic immunotherapy; a proposal in development with Chee Lee and Mark Pinkham. A previous design of this study and an updated proposal has been sent to TROG for input and feedback.

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. Oligo-metastatic disease, an evolving concept, is where cancers have spread but have not developed the full capabilities of widespread dissemination.

In metastatic/Stage 4 disease, local radiation has traditionally been given for symptom-control but is not known to improve survival. Recently, there has been a significant increase in stereotactic radiation which offers more precise delivery, higher total dose and dose per fraction, and high (80–90%) local control vs conventional radiation. This leads to shorter treatment time and increases convenience for the patient.

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 improves progression-free and overall survival in Stage 4 disease which has been demonstrated by several phase 2 studies. 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 hypothesis is that earlier treatment with stereotactic therapy is beneficial vs later treatment at progression by:

- Cytoreduction – removing resistant clones and reducing the ability to evolve
- Improving in-field local control
- Improving out-of-field failure

The proposed study is a prospective phase 2/3 randomised 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 in up to five lesions in three organ sites and systemic therapy will be continued
- 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
- The proposed intervention sample size for the phase 2 study will be 60 participants; this provides >90% power with 95% confidence to exclude 50% in favour of 70%
- If the primary endpoint is met in the phase 2 study and the study is deemed feasible, the study will progress to a second phase 3 component to examine the difference in overall survival. Accounting for a 3-year overall survival rate of 50% in the control group, a sample size of 520 participants will be required to provide 80% power with 95% confidence to detect a 30% relative reduction in death in the intervention group

Aspects currently for discussion include:

- **Attribution:** this study will determine whether early stereotactic radiation improved survival, but will not determine the effects on a particular lesion
- **Inclusion of participants:**
    - **with oligo-progressive disease:** those with clear oligo-progressive disease are often treated and therefore would be difficult to randomise
    - **on chemotherapy:** considering the potential combined toxicities, it was suggested that the study should not include participants receiving concurrent chemotherapy (prior chemotherapy would be acceptable)
- **How treatment is working:** it was suggested to not only interpret whether treatment is working but how it is working

- **Novelty of study**: with many published and ongoing trials, this trial aims to determine whether earlier stereotactic therapy is beneficial vs later treatment
    - **Visual aid:** it was suggested that a visual aid that quickly demonstrates the point(s) of difference of the study would be helpful when submitting for a grant application

Concept review and peer input for future submissions

Computational drug repurposing in advanced cancers

Malaka Ameratunga (Oncologist, Alfred Health/Monash University) presented a proposal for repurposing treatments in patients with advanced cancers with poor prognosis and no standard therapy is available.

There is a lack of incremental progress and no clinical learning for patients who have reached palliative treatment and therefore, an alternative theoretical paradigm exists. It involves consenting the patient for rapid next-generation sequencing for molecular tumour board assessment. Patients with validated targets and licensed therapies available to them will be offered treatment while those with a non-validated potential target will undergo *in silico* analysis for drug repurposing. Should a therapy be found that has demonstrated to be safe and tolerable, it may be offered to the patient (subject to funding). Probeminer is a repurposing platform that mines for ligand-receptor interactions and then quantitatively ranks targets.

This pilot study proposes to rapidly sequence eligible participants for molecular tumour board and then undergo *in silico* analysis to determine whether there is a repurposing event. Those found to have a repurposing event will seek approval for therapy and be radiologically assessed for progression.

- The study will use a Simon two stage design where, to proceed to the second stage, one response is required in the first 30 participants and five responses in 52 total participants would be required to further investigate the approach
- The primary endpoint is overall response rate via RECIST 1.1 measures and the secondary endpoint is the percentage of participants who are evaluable for disease response with a computationally repurposed drug
- Agreement for sequencing funding is in process
- There is need to access multiple different drugs and potentially, unanticipated drugs too; agreements with some pharmaceutical companies (e.g, via compassionate access) will be in place

GeneScreen 5-FU – DPYD guided genotyping for fluoropyrimidine prescribing

Steve Ackland (Medical Oncologist) presented a proposal for GeneScreen, which is proposed to demonstrate the cost effectiveness of DPYD genotyping in patients who may be prescribed fluoropyrimidine. The proposal is in development with Cass White, Rodney Scott and Chris Paul and has been presented and is endorsed by AGITG. By personalising treatment, e.g. dose alteration, toxicity may be reduced and unpredictable toxicity may be avoided.

Fluoropyrimidines are widely used in the treatment of gastrointestinal, breast, head and neck cancers, however, up to 30% of patients prescribed fluoropyrimidines will experience side effects of Grade 3 and above (mucositis, diarrhoea, myelosuppression, hand and foot syndrome).

The DPYD gene encodes for DPD, which is the first enzyme in the catabolic pathway of 5-fluorouracil (5-FU). Those with reduced DPD activity have increased cytotoxic metabolites and risk of toxicity. Over 160 variants of DPYD have been identified, of which four main functional variants have been identified in Caucasians. Some variants are known to have no functional effect on the allele and some, only partial function. The gene activity score combines the activity of both alleles and indicates whether an individual would be a normal, intermediate or poor metaboliser (of the drug, 5-FU).

This proposed study investigates the cost-effectiveness of genotyping DPYD to personalise dosing of 5-FU for those identified with one of the four main functional variants identified in Caucasians to reduce mortality, toxicity and the frequency of toxicity.

- A study conducted in the Netherlands involving 180 participants has demonstrated feasibility and improved safety
- DPYD screening prior to fluoropyrimidine chemotherapy has been recommended in countries such as the UK, Netherlands, France and Switzerland, and also in the European Society of Medical Oncology (ESMO) guidelines for colorectal cancer, however, the FDA and TGA have no recommendations yet
- The proposed study will be an implementation science project aiming to demonstrate success and sustainability, so DPYD screening becomes normal practice in Australia

- Currently, a feasibility study is being conducted. Blood samples are taken for genotyping and the primary endpoint is the genotype turnaround time. To date, 60 participants have been recruited, of which 9 patients have been found to carry DPYD variants. The real-time polymerase chain reaction (RT-PCR) technique has been optimised to be able to screen for all four variants. The average genotype turnaround time is 6.86 days
- The next study proposed aims to recruit and genotype 500–3000 participants. 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

Alternative funding strategies and sources

John Simes (NHMRC CTC) spoke about some issues and alternative strategies for applying for funding for clinical trials, of which were spoken about in the morning session.

NHMRC Clinical Trials and Cohort Studies grant:

- Generally appropriate for larger practice-changing trials (phase 3)
- A success rate of 5.4% previously improving to 11% in last round
- Many (possibly ~40–50%) applications rated as not for further consideration

NHMRC ideas grant:

- Appropriate for early phase trials and/or translational sub-studies
- A success rate of 9.5%; from 2020 onwards, none or few applications were rated as not for further consideration and were given a score

Cancer Australia (priority-driven collaborative cancer research scheme)

- Consider both NHMRC schemes if aiming for a Cancer Australia grant

MRFF grant:

- Several categories including rare cancers, rare diseases and unmet need, bringing international trials to Australia and effective therapies category

NHMRC investigator grant:

- Appropriate for pilot phase trial or to support translational research linked to clinical trial

Other schemes:

- Grant schemes from pharmaceutical companies
- Wellcome

- Philanthropic
- Partnerships

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Workshop evaluation

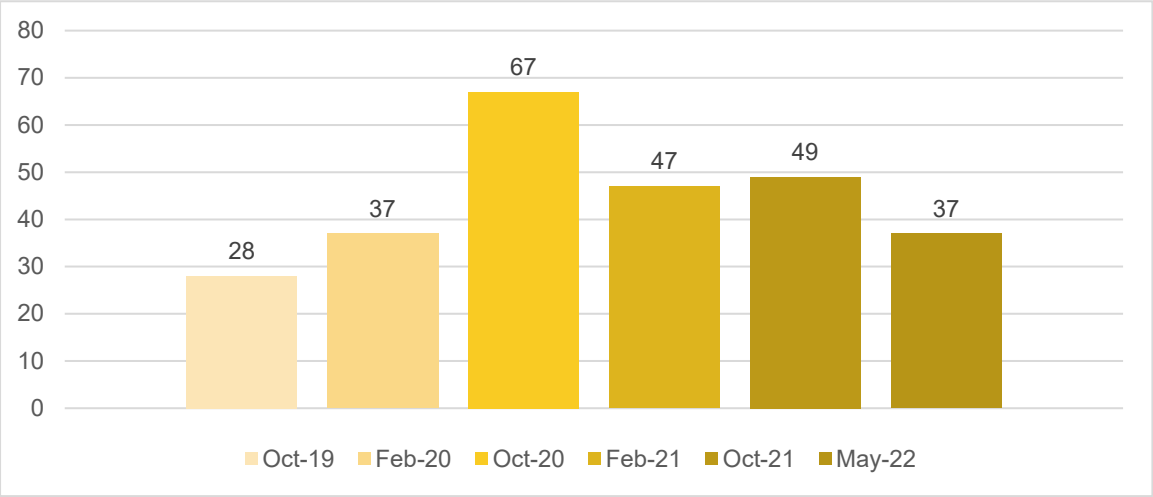
Introduction

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 May 2022 workshop.

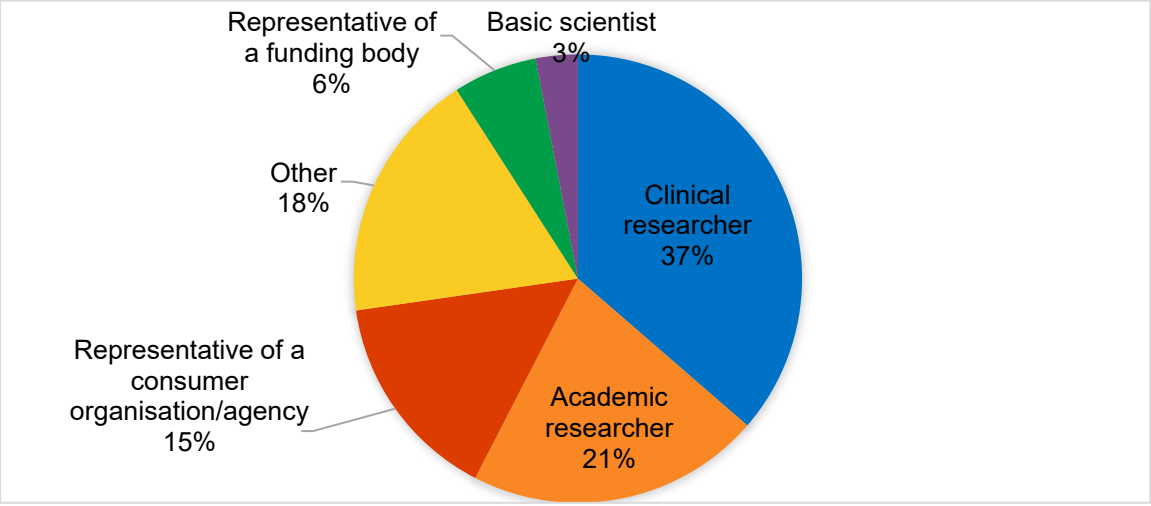
Figure 1: Number of participants at GCCTI workshops (frequency)



Nineteen of the 37 participants who attended the workshop completed the survey (a 51% response rate), a decrease in the response rate from the previous workshop, which was 53%.

The majority of survey respondents identified as clinical researchers (60%), followed by academic researchers (35%).

Figure 2: Participant roles (frequency and proportion)



Organisations/groups in attendance

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

- Alfred Health, VIC
- Cancer Australia
- Canterbury Health Laboratories, NZ
- Commonwealth Department of Health
- Garvan Institute of Medical Research, NSW
- Gastrointestinal Cancer Institute, NSW
- Liverpool Cancer Therapy Centre, NSW
- Metro North Health, QLD
- Monash University, VIC
- NHMRC Clinical Trials Centre, NSW
- Peter MacCallum Cancer Centre, VIC
- St Vincent's Hospital, VIC
- South East Regional Hospital, NSW
- The University of Melbourne, VIC
- The University of Sydney, NSW
- University of Technology Sydney (UTS), NSW
- Westmead Institute for Medical Research (WIMR)
- Cancer service – CQUEST
- Cooperative Clinical Trials Groups (CTGs)
    1. AGITG
    2. ANZGOG
    3. ANZUP
    4. COGNO
    5. PC4
    6. PaCCSC & CST
    7. TOGA
    8. TROG
    9. ANZCHOG

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Understanding the workshop's aim and purpose

74% of respondents indicated that they had a clear understanding of the aims and purpose of the workshop.

32% of respondents ‘agreed’, and 42% of respondents ‘strongly agreed’. 26% of respondents were ‘undecided’. Respondents noted:

"Excellent workshop - the first session was particularly fantastic, but I also loved hearing all the trials being presented"

"Probably specify that it was more concept development workshop"

Usefulness and relevance of the presentations

84% of respondents indicated that they found the content of the workshop presentations useful and relevant.

37% of respondents ‘agreed’, and 47% of respondents ‘strongly agreed’. One respondent noted:

"If I had been able to, I would have liked to have been able to stay for the whole workshop to listen to more of the presentations. It’s valuable as a funder to have insight into the process for developing grant proposals"

Organisation of workshop

95% of respondents indicated that the workshop was well organised

42% of respondents ‘agreed’, and 47% of respondents ‘strongly agreed’; one respondent did not respond. One respondent noted:

“Probably shorter lunch break”

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: what’s new and helpful for grant-writers (63%)

- Grant review and peer input for submissions (58%), in particular, four respondents found the input, detailed questions and discussion useful
- Alternative funding sources (21%)

One respondent noted:

"Detailed questions from audience of study concepts and discussions - especially sharing of experiences of researchers in similar space."

Additional comments/suggestions to enhance future workshops

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

- Reviewers such as the mock grant review panel or assigning a dedicated reviewer to concepts
- Moving back to face-to-face meeting
- Ensuring enough participation from genomics experts
- Missing representation and input from some cooperative groups
- Consolidating introduction of workshop participants

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Appendix: Workshop agenda

Venue	Virtual Workshop via Zoom
Date	Friday 6 May 2022
Time	9.00am – 3.00pm
Purpose	To strengthen grants applications for submission in 2022 and beyond

Time	Session	Presenter
9:00–9:15am	*Log in and registration*	
9:15–9:30am	**Welcome and introductions**	*Martin Stockler*
	Overview of GCCTI and achievements to date	*Martin Stockler*
9:30–10:15am	**Grants Update: what's new and helpful for grant-writers**	
	• MRFF – Cancer Clinical Trial Grant Opportunities • NHMRC – Clinical Trials and Cohort Studies • Cancer Australia - Priority-driven Collaborative Cancer Research Scheme	*Ruth Webster* *Wee-Ming Boon* *Gayle Jones*
10:15am–10:30am	*Morning Tea*	
10:30am–12:30pm	**Grant review and peer input for 2022 submissions**	*Group Discussion*
	*Attendees present grant applications proposed for submission in 2022** *to receive feedback from expert peers reflecting NHMRC criteria and processes.* **proposed grants need not be eligible for GCCTI support.*	
	Randomised trial of denosumab with immune checkpoint inhibitors	*Angelina Tjokrowidjaja*
	Intraperitoneal anti-VEGF for recurrent, malignant ascites	*Katherine Francis*
	Stereotactic radiation as consolidation following immunotherapy	*Eric Hau*
12:30–1:30pm	*Lunch*	
1:30–2:45pm	**Concept review and peer input for future submissions**	*Group Discussion*
	Computational drug repurposing in advanced cancers	*Malaka Ameratunga*
		TBD
	Alternative funding strategies and sources	*John Simes*
2:45–3:00pm	**Wrap-up and close**	*Martin Stockler*