



Genomic Cancer
Clinical Trials Initiative

Genomic Cancer Clinical Trials Initiative

April 2024 Workshop Report

The Genomic Cancer Clinical Trials Initiative (GCCTI) is a technical service delivered as a partnership between the NHMRC Clinical Trials Centre, University of Sydney and Zest, and funded by Cancer Australia.

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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 **Grant Development Workshop** on **Friday 12 April 2024** at the Chris O'Brien Lifehouse, Sydney; hybrid attendance was also made available via Teams.

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 2024 and beyond.

Objectives for workshop participants:

- Learn about current grant opportunities, guidelines, assessment criteria and recent changes
- Be kept up-to-date with concepts presented previously
- Present synopses of grants or ideas for submission for feedback from peers and development groups
- Discuss and generate ideas for grants to submit beyond 2024, especially those including multiple cancer types and multiple CCTGs



The workshop program is included in the [Appendix](#)

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

Funding updates

Update on Medical Research Future Fund (MRFF) grants programs

Dr Jordane Malaterre (A/g Director, Patients and Infrastructure, Health and Medical Research Office)

The MRFF's Clinical Trials Activity Initiative includes \$750 million of funding over 10 years from 2022–23. The initiative aims to increase clinical trial activity in Australia; funding areas such as rare cancers, rare diseases and unmet need priority areas.

Current MRFF opportunities are listed in the table below.

<p>2023 MRFF Clinical Trials Activity Grant Opportunity</p>	<ul style="list-style-type: none"> • Now open and will close 29 May 2024; full guidelines found here • Includes up to \$65 million for areas such as: <ul style="list-style-type: none"> ○ Conduct a pilot study to assess the feasibility of a new clinical trial for one or more treatments and/or management strategies for a rare cancer, rare disease and/or unmet need (new) ○ Conduct a clinical trial of one or more treatments and/or management-based interventions for rare cancers, rare diseases and/or unmet need ○ Conduct a clinical trial that assess the comparative effectiveness of two or more health interventions (not placebo-controlled) to treat a specific clinical condition ○ Conduct an implementation science trial to identify scalable strategies for reducing the provision of low value care
<p>2024 MRFF International Clinical Trials Collaborations</p>	<ul style="list-style-type: none"> • Now open and will close 31 July 2024 (round 1) and 5 February 2025 (round 2); full guidelines found here • Includes up to \$12.6 million for areas that: <ul style="list-style-type: none"> ○ Promotes Australian involvement in international collaborative investigator-initiated clinical trials research through the establishment and co-ordination of clinical trial site/s in Australia ○ Provides high-quality evidence of the effectiveness of novel health treatments, drugs or devices in 'usual care' settings, which will support a decision on whether to deliver the intervention in an Australian setting
<p>2023 MRFF Innovative Trials Grant Opportunity</p>	<ul style="list-style-type: none"> • Now open and will close 10 July 2024; full guidelines found here • Includes up to \$23.7 million for projects that: <ul style="list-style-type: none"> ○ Address an area of unmet medical need by promoting the development and implementation of adaptive platform trials

	<ul style="list-style-type: none"> ○ Conduct a registry-based randomised controlled trial in an area of unmet medical need by embedding a registry-based randomised controlled trial into a pre-existing clinical registry ○ Generate evidence of the efficiency and cost effectiveness of innovative trial designs over conventional trial designs for adaptive platform trials/registry-based randomised controlled trials
MRFF's Clinical Trial Activity Evaluation	<ul style="list-style-type: none"> ● The Department of Health and Aged Care engaged the Institute for Evidence-Based Healthcare (IEBH) to evaluate the MRFF Clinical Trial Activity initiative and other MRFF-funded clinical trials; please refer to the presentation here for key findings

Update on Clinical Trials and Cohort Studies (CTCS) grants programs

Dr Wee-Ming Boon (Director, Translation Programs, Research Partnerships Branch, NHMRC) and Ms Sarah Hazell (A/g Assistant Director)

The Clinical Trials and Cohort Studies receives an annual allocation of approximately \$70–75 million and supports approximately 30 grants per round.

The peer review process is a 2-step process:

1. Each application is assessed by up to three independent experts
2. The top 30% of applications will then be discussed and reassessed by a peer review panel for ranking

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.

From 2019 until 2022 (2023 TBA):

- The funded rates were 5.4%, 6.9%, 11.3% and 11.6%, respectively
- The mean budget requested ranged between \$1.8 and \$2.4 million (\$2.8 million in 2023) and mean granted budget ranged between \$2.3 million and \$2.6 million
- Aboriginal and Torres Strait Islanders health applications did very well

In 2023, CTCS recommends:

- Enhancing significance by telling a good story and provide a strong rationale that is supported by evidence and meaningful consumer and community involvement
- Having realistic milestones & performance indicators
- Providing a good implementation plan while managing and mitigating risks
- Proposing an appropriate budget that matches the scope and scale of the project

Applicants are encouraged to refer to the following:

- SPIRIT Statement items (<https://www.spirit-statement.org/spirit-statement>)
- STROBE reporting standard (<https://www.strobe-statement.org>)

For tips on preparing a CTCS application and what high and low scoring applications look like, please refer to the presentation [here](#).

Update on Cancer Australia Research Investment

Mr Adam Lambert (Director, Clinical trials and community support, Evidence, Priority Initiatives Communications Branch, Cancer Australia)

Cancer Australia's Priority-driven Collaborative Cancer Research Scheme (PdCCRS) will be paused for 2024.

In consultation with funding partners and stakeholders, the research investment program is undergoing redesign; new grant opportunities for collaborative clinical trials groups will be announced in due course.

Workshop participants are encouraged to attend the Australian Comprehensive Cancer Network Innovations Showcase; 21 May 2024 (hybrid conference format; Rydges World Square, Sydney). Registrations open [here](#).

Progress updates from previous presented concepts

Intraperitoneal bevacizumab for recurrent, malignant ascites (REZOLV3R)

A/Prof Katrin Sjoquist (Medical Oncologist) presented an update on the REZOLV3R (which follows the completed [REZOLVE](#) trial). This proposal was presented at previous GCCTI Workshops (May 2022, March and October 2023) and involves input from various CCTGs including, Cancer Symptom Trials (CST), Australasian Gastro-Intestinal Trials Group (AGITG), and Australia New Zealand Gynaecological Oncology Group (ANZGOG).

REZOLV3R has received pilot funding (NHMRC CTC program grant). In 2023, REZOLV3R received funding from Cancer Australia for 10 Australian sites with up to 100 participants. REZOLV3R was resubmitted as an NHMRC CTCS grant in 2023.

The protocol has been approved and site selection/start up is underway with site initiation visits anticipated in May 2024.

View the presentation [here](#).

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

Professor Steve Ackland (Medical Oncologist) presented an update on a proposal for GENESCREEN to demonstrate the cost effectiveness of DPYD genotyping in patients who may be prescribed fluoropyrimidine (FP) and irinotecan. This proposal has been presented at previous GCCTI Workshops in 2022 and 2023.

The GENESCREEN feasibility study is complete (n=101). In 2023, GENESCREEN-5FU received funding from MRFF for an interventional study which aims to recruit 5000 participants starting Q2 2024.

To learn more about GENESCREEN, view the presentation [here](#).

Ventilation Imaging to improve the quality of life for patients with Lung cancer treated with radiation therapy (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 3 lung cancer. VITaL was presented at previous GCCTI Workshops in March and October 2023 and will be resubmitted as an NHMRC CTCS application in 2024.

View the presentation [here](#).

Precision medicine platform for Aboriginal and Torres Strait Islander people

Prof Alex Brown (Professor and Head of Indigenous Genomics, Telethon Kids Institute and ANU and Head of ALIGN, Australian Alliance for Indigenous Genomics)

This presentation has been postponed until the next GCCTI Workshop, 25 October 2024.

Omico, MoST, and PrOSPeCT update

Prof David Thomas (CEO, Omico)

This presentation provided an update of the Australian landscape in precision oncology, in particular PrOSPeCT, and spoke about opportunities for genomic-based clinical trials (both investigator- and industry-led studies).

For updates and more information, please view the presentation found [here](#).

Trial concepts for peer review

Four evolving concepts/grant applications were presented at the workshop which were reviewed by peers. Members interested in finding out more or to discuss collaboration opportunities, please contact the presenter directly.

- **Opioid pharmacogenomics registry trial for cancer pain (OPPtC-2)**
Dr Aaron K Wong, Palliative Care Physician and Medical Oncologist; Clinical Trials Lead, Palliative Care, Peter MacCallum Cancer Centre & The Royal Melbourne Hospital
Email: Aaron.Wong@petermac.org
- **Addition of stereotactic radiosurgery to molecular targeted therapies in driver mutation positive non-small cell lung cancer with persistent or progressive brain metastases (OUTRUN-P²)**
Dr Yu Yang Soon, Radiation Oncologist, National University Cancer Institute & National University Hospital, Singapore and NHMRC Clinical Trials Centre, University of Sydney
Email: yu.soon@sydney.edu.au
- **Neoadjuvant radiotherapy: Improving responses to neoadjuvant chemo/immunotherapy in resectable NSCLC with high precision radiotherapy**
Dr Fiona Hegi-Johnson, Director TROG Board and Chair; TROG Lung Working Party; Senior Research Fellow, University of Melbourne
Email: fiona.hegi-johnson@petermac.org
- **Investigation of microbiome genomic signature associated with immune-related adverse events and response in patients with advanced cancer treated with anti-cancer immune checkpoint inhibitors**
Dr Sonia Yip, Translational Research Lead, Senior Research Fellow, NHMRC Clinical Trials Centre, University of Sydney
Email: sonia.yip@sydney.edu.au

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

Forty participants attended the GCCTI April 2024 workshop; 18 participants (45%) attended in-person and 22 participants (55%) attended virtually.

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

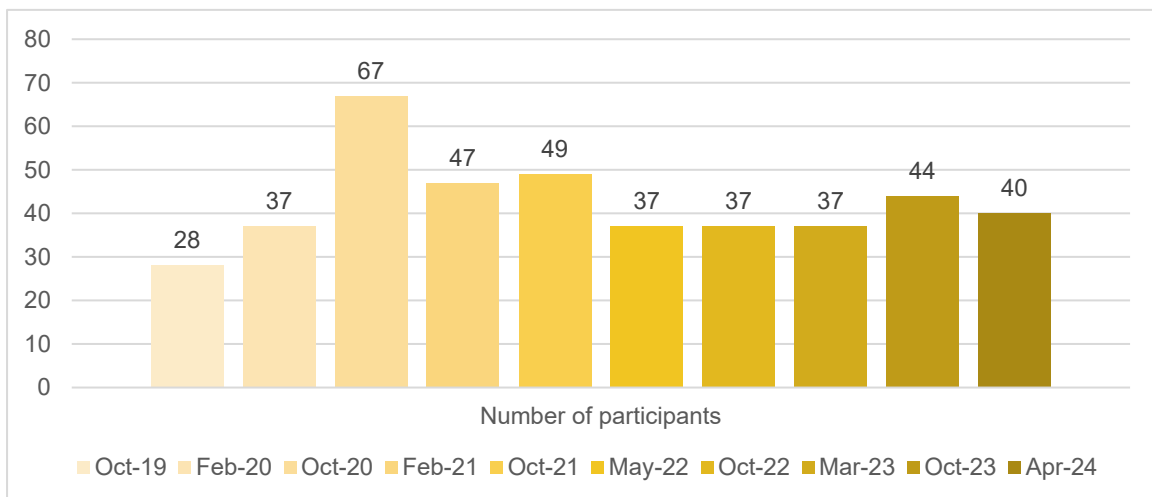
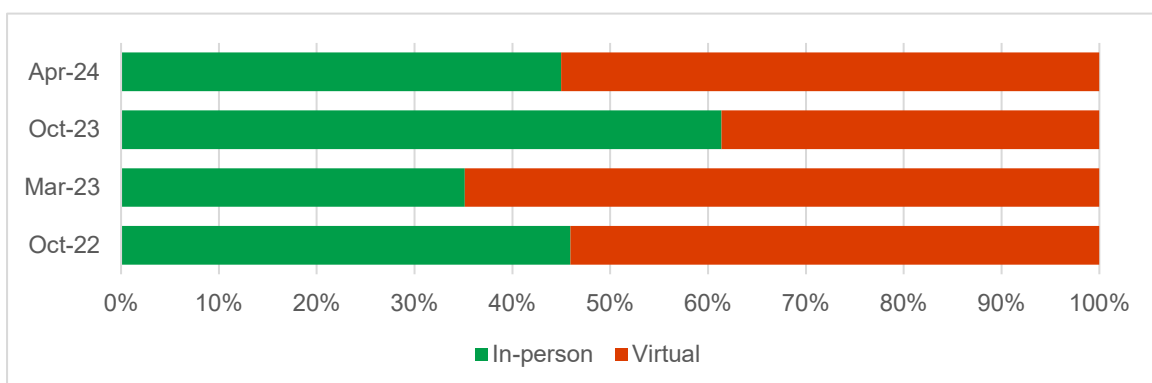


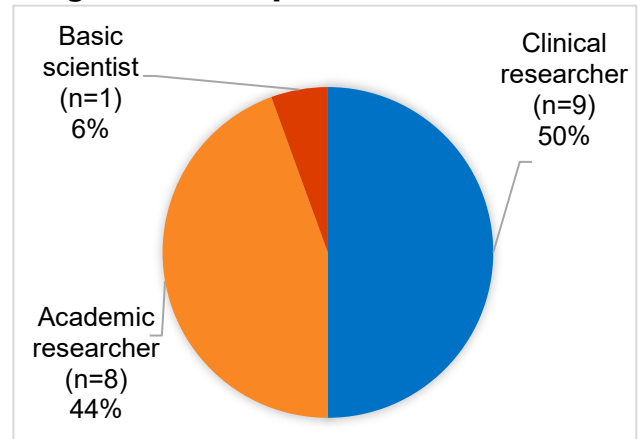
Figure 2: Hybrid meeting attendance method



Fifteen of the 40 participants who attended the workshop completed the survey (a 37.5% response rate), a decrease in the response rate from the previous workshop, which was 43%.

The majority of survey respondents identified as clinical researchers (56%), followed by academic researchers (50%).

Figure 3: Participant roles



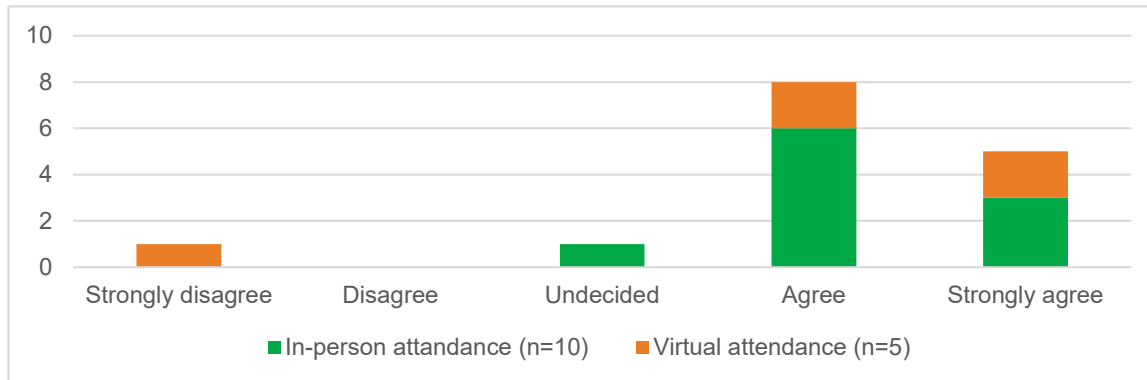
Organisations/groups in attendance

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

- Ballarat Regional Integrated Cancer Centre
- Cancer Australia
- Commonwealth Department of Health
- Fiona Stanley Hospital, WA
- Ingham Institute
- NHMRC
- NHMRC Clinical Trials Centre, NSW
- Omico (Kinghorn Cancer Centre, NSW)
- Peter MacCallum Cancer Centre, VIC
- Royal North Shore Hospital
- Royal Prince Alfred Hospital
- SA pathology (Flinders Medical Centre)
- St George Hospital, NSW
- Telethon Kids Institute, WA
- The University of Newcastle, NSW
- The University of Sydney, NSW
- Cooperative Clinical Trials Groups (CCTGs)
 1. AGITG
 2. ANZCHOG
 3. ANZUP
 4. BCT
 5. COGNO
 6. PaCCSC & CST
 7. PC4
 8. PoCoG
 9. TOGA
 10. TROG

Understanding the workshop's aim and purpose

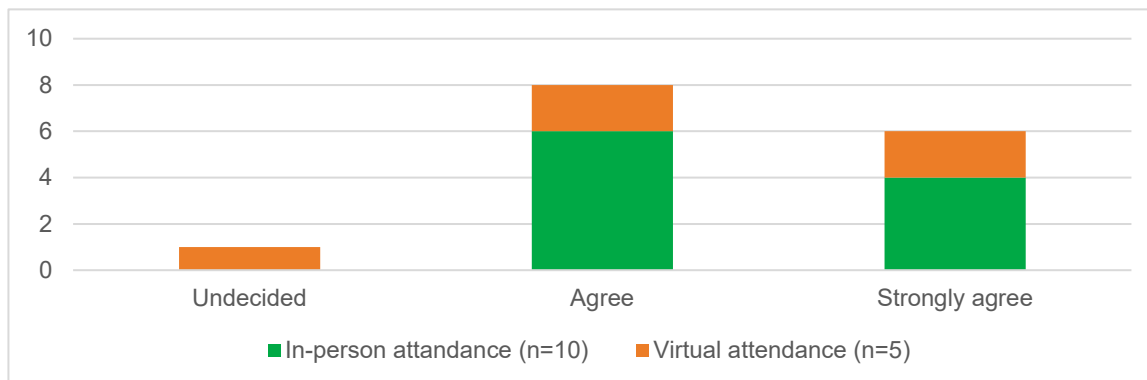
Figure 4: Number of participants that understood the aim and purpose of the workshop



86.7% of respondents indicated that they had a clear understanding of the aims and purpose of the workshop.

Usefulness and relevance of the presentations

Figure 5: Number of participants that found the content useful and relevant



93.3% of respondents indicated that they found the content of the workshop presentations useful and relevant. Respondents noted:

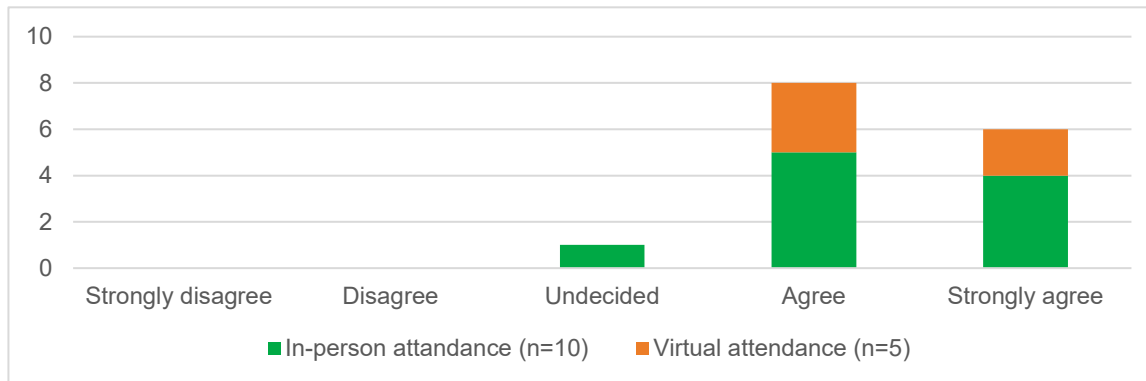
"I always enjoy the beginning in which I gain insights into making the grants more competitive"
– In-person attendee

"Updates of findings and discussion of final proposals" – Virtual attendee

"Discussion and reviews of new trial ideas" – Virtual attendee

Organisation of workshop

Figure 6: Number of participants that found the hybrid format to work well



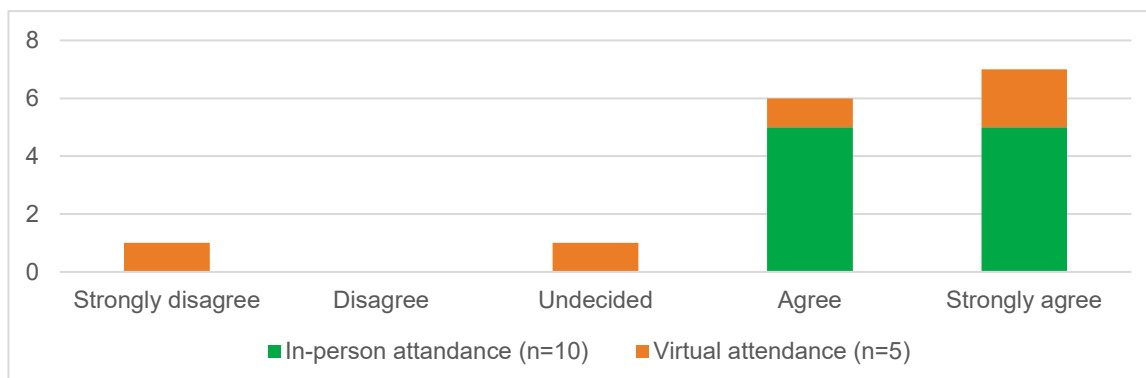
93.3% of respondents indicated that the hybrid format worked well. Respondents noted:

“While I understand the benefits of hybrid, I find it more engaging to be full face to face”
– In-person attendee

*“It is great that online is offered for those based outside Sydney.
Difficult to find time to travel to every meeting”* – In-person attendee

“Camera in seminar room not working” – Virtual attendee

Figure 7: Number of participants that found the workshop well organised



86.7% of respondents indicated that the workshop was well organised. One respondent noted:

“The half-day format was good. It was well organised and well run” – Virtual attendee

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:

- Trial concepts for review and discussion (73%)
- Funding updates (40%)
- PrOSPeCT update (13%)
- Progress from previous presented concepts (7%).

Respondents noted:

“I found that having reviewers of the concepts useful and I liked the variety of talks.”

“More about immune checkpoint inhibitors”

“Good to see progress of previous trial progress”

“Funding updates was very helpful, as well as peer review of trial concepts”

“Overall mix”

Additional comments/suggestions to enhance future workshops

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

Organisation

- Earlier invitation
- Camera in seminar room

Workshop format

- More time for discussion/questions for trial proposals

Topics

- A discussion about barriers to research involving multiple cancer types and how to overcome them
- Talks by methodologist and health economics
- How to get started in designing platform trials



Appendix: Workshop agenda

Genomic Cancer Clinical Trials Initiative Grant Development Workshop Program

Venue Education Room, Chris O'Brien Lifehouse and via Zoom
Date Friday 12 April 2024
Time 9.00 am – 1.00 pm
Purpose To strengthen grants applications for submission in 2024 and beyond

Time	Session	Presenter
9:00–9:15 am	Registrations	
9:15–9:25 am	Welcome and introductions Overview of GCCTI and achievements to date	<i>Katrin Sjoquist</i>
9:25–10:05 am	Funding updates: what's new and helpful for grant-writers <i>Chair: Katrin Sjoquist</i>	
	<ul style="list-style-type: none"> MRFF – Cancer Clinical Trial Grant Opportunities NHMRC – Clinical Trials and Cohort Studies Updates from Cancer Australia 	<i>Jordane Malaterre Wee-Ming Boon & Sarah Hazell Adam Lambert</i>
10:05–10:35 am	Progress updates from previous presented concepts <i>Chair: John Simes</i>	
	<ul style="list-style-type: none"> REZOLV3R GENESCREEN VITaL 	<i>Katrin Sjoquist Steve Ackland Paul Keall</i>
10:35–10:50 am	Precision medicine platform for Aboriginal and Torres Strait Islander people <i>Chair: John Simes</i>	<i>Alex Brown</i>
10:50–11:10 am	PrOSPeCT update <i>Chair: John Simes</i>	<i>David Thomas</i>
11:10–11:30 am	<i>Break</i>	
11:30–12:50 pm	Trial concepts for peer review <i>Chair: Katrin Sjoquist</i>	<i>Group Discussion</i>
	<i>Attendees present evolving concepts or grant applications to receive feedback from expert peers reflecting NHMRC criteria and processes.</i>	
	<ul style="list-style-type: none"> Opioid Pharmacogenomics Registry Trial for Cancer Pain (OPPtC-2) Stereotactic radiation for genomic-driven brain metastases Neoadjuvant radiotherapy: Improving responses to neoadjuvant chemo/immunotherapy in resectable NSCLC with high precision radiotherapy 	<i>Aaron Wong Yu Yang Soon Fiona Hegi-Johnson</i>
12:50–1:00 pm	Wrap-up and close	<i>Katrin Sjoquist</i>