Genomic Cancer
Clinical Trials Initiative

Genomic Cancer Clinical Trials Initiative

October 2024 Research Development Workshop Report

The Genomic Cancer Clinical Trials Initiative (GCCTI) is a technical service delivered as a partnership between NHMRC Clinical Trials Centre 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 one-day in-person **Research Development Workshop** on **Friday 25 October 2024** at the Chris O'Brien Lifehouse.

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 and generate ideas and opportunities for studies and grants involving cancers from multiple primary sites and multiple CCTGs.

The October 2024 workshop provided a forum for key stakeholders to:

- Learn about the latest changes in grant opportunities for clinical cancer research
- Explore new topics and generate ideas with applicability to multiple cancer types and CCTGs
- Discuss ideas and proposals for studies that could involve multiple cancer types and CCTGs
- Identify opportunities for collaboration across cancer types and 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

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Session 1:
PrOSPeCT and Omico updates

Prof David Thomas (Inaugural Director of the Centre for Molecular Oncology, UNSW and Head of the Genomic Cancer Medicine Laboratory, Garvan Institute of Medical Research)

This presentation provided updates on PrOSPeCT and Omico, and spoke about opportunities for genomic-based clinical trials. In particular, designing clinical trials to generate data for submission to regulatory bodies (e.g. Pharmaceutical and Medicare Benefits Scheme) for rare pan-cancers, which account for similar number of cancer deaths as lung cancer.

For more information, please view the presentation found here.

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Session 2:
Updates from previous workshops

Osimertinib with or without stereotactic radiosurgery for brain metastases from epidermal growth factor mutated non-small-cell lung cancer: Pooled analysis of two randomised controlled trials (LUOSICNS and OUTRUN)

Dr Yu Yang Soon (Radiation Oncologist) presented an update of a pooled analyses of two randomised controlled trials, LUOSICNS and OUTRUN. These studies had a similar study design and primary outcomes but slightly varied patient eligibility criteria. There was insufficient evidence to demonstrate a difference between upfront vs no upfront stereotactic radiosurgery.

The next steps will explore how to combine local therapy with the evolving molecular treatments available.

Please view the presentation found here, or for collaboration opportunities, updates and information, please email Yu Yang Soon at Yu.Soon@sydney.edu.au.

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 (AUTO-CHECK microbiome)

Dr Sonia Yip (Translational Research Lead) presented a concept that extends the GCCTI-supported AUTO-CHECK study (more information here). This concept leverages whole blood and plasma samples, already collected as part of the AUTO-CHECK study, to investigate a microbiome signature (genomic, proteomic) associated with immune-related adverse events (IRAE) and response in patients with advanced cancer treated with anti-cancer immune checkpoint inhibitors.

For collaboration opportunities, updates and information, please email Sonia Yip at Sonia.Yip@sydney.edu.au.

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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). REZOLV3R received funding from NHMRC CTC program grant (pilot funding) and Cancer Australia. This proposal involved input from various CCTGs including, Cancer Symptom Trials (CST), Australasian Gastro-Intestinal Trials Group (AGITG), and Australia New Zealand Gynaecological Oncology Group (ANZGOG).

REZOLV3R aims to recruit 100 participants across 3 years in 10 Australian sites (metropolitan and regional). Currently there is one active site (recruitments are open via this link) and 4 sites in start-up.

Please view the presentation found here, or for updates and information, please email rezolv3r.study@sydney.edu.au.

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Session 3: Updates from selected CCTGs and groups

Updates from Trans-Tasman Radiation Oncology Group (TROG)

Dr Joseph Sia (TROG:GCCTI representative and Radiation Oncologist)

Dr Sia provided an overview of TROG and shared some current concepts in early development within TROG that may interest other CCTGs.

For updates, information and collaboration opportunities with TROG, please email Joe Sia at joseph.sia@petermac.org.

Updates from Psycho-Oncology Cooperative Research Group (PoCoG)

Dr Nicole Bartley (PoCoG:GCCTI representative and Post-doctoral Research Associate)

Dr Bartley provided an overview of PoCoG and presented some suggestions on ways to collaborate with PoCoG.

More information in the presentation found here. For updates, information and collaboration opportunities with PoCoG, please email Nicci Bartley at nicole.bartley@sydney.edu.au.

Updates from Australian and New Zealand Urogenital and Prostate Trials group (ANZUP)

Dr Vinod Subhash (Translational Research Operations Manager, ANZUP)

Dr Subhash provided an overview of ANZUP and shared an update of an ANZUP-sponsored start up clinical trial, GenI-AIRSPACE (Genomically Informed Active Surveillance in Favourable Intermediate Risk Prostate Cancer).

More information in the presentation found here. For updates, information and collaboration opportunities with ANZUP, please email Vinod Subhash at vinod.subhash@anzup.org.au.

Updates from Australiasian Leukaemia and Lymphoma Group (ALLG)

Ms Delaine Smith (CEO, ALLG), via video presentation

Ms Smith provided an overview of ALLG. For updates, information and collaboration opportunities with ALLG, please email Tracey Gerber at tracey.gerber@allg.org.au.

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Session 4:
Management of brain metastases from multiple cancer types

Dr Yu Yang Soon (Radiation Oncologist, National University Cancer Institute & National University Hospital, Singapore and NHMRC Clinical Trials Centre, University of Sydney)

This presentation shared emerging evidence and current trials for management of brain metastases to generate discussion and ideas for development of a platform trial for brain metastases across multiple cancer types. Specifically, integrating systemic therapy or brain-directed therapy with radiation for the treatment of brain metastases.

According to practice guidelines (published 2021), the optimal time to use local therapy (or defer local therapy) is unclear with only a weak classification in strength of recommendation. However, there are rapidly developing evidence for new CNS active systemic therapies (EGFR mutated non-small cell lung cancer: FLAURA 2 and MARIPOSA, and post-osimertinib: MARIPOSA-2). The next generation of trials for brain metastases will likely aim to assess the effects of artificial intelligence-based approaches in personalising brain metastasis-directed therapies using standardised disease-related and/or patient reported outcomes.

Please view the presentation found here for more details, and for updates, information and collaboration opportunities, please email Yu Yang Soon at Yu.Soon@sydney.edu.au.

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Session 5: Grants update

New developments around the relaunch of Priority-driven Collaborative Cancer Research Scheme (PdCCRS)

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

The activities of Cancer Australia are all aligned with the 10-year Australian Cancer Plan. This includes the Support for Cancer Clinical Trials Program (SCCT) that provides funding to multi-site Collaborative Cancer Clinical Trials Groups. A new 3-year funding period (2024–26) was announced in October 2024.

In 2024, Cancer Australia's Priority-driven Collaborative Cancer Research Scheme (PdCCRS) was paused for 2024–25 to allow for re-designing the scheme to align with the Australian Cancer Plan. A new research investment program for grant opportunities will open in 2025–26 and more will be announced in the near future.

To learn more about Cancer Australia's Research in investment, view the presentation here and visit the website here.

Medical Research Future Fund (MRFF)

Dr Vicky Dong (Director, Patients and Infrastructure Section, Health and Medical Research Division, Department of Health and Aged Care), via report submission

The Medical Research Future Fund (MRFF) operates as an endowment fund, with decisions regarding its expenditure set by the Australian Medical Research Innovation Strategy 2021–2026 (the Strategy) and the Australian Medical Research and Innovation Priorities 2022–2024 (the Priorities). These have been developed by the independent and expert Australian Medical Research Advisory Board (AMRAB) following national public consultation.

Grant opportunities under the MRFF

The $6.5 billion 3rd 10-year Investment Plan (2024–25 to 2033–34) for the MRFF was released in May 2024, and provides funding for 22 Initiatives to support lifesaving research and further grow Australia's reputation as a world leader in medical research.

Relevant MRFF Initiatives with currently open grant opportunities include:

- The **Clinical Trials Activity Initiative**, which provides $750 million over 10 years from 2024–25 and aims to:
  - improve the evidence base supporting clinical care
  - help patients access trials relevant to their health circumstances, and
  - enable researchers to bring international trials to Australian patients.
- The **National Critical Research Infrastructure Initiative**, which provides $600 million over 10 years from 2024–25 and aims to establish and extend infrastructure (facilities, equipment, systems and services) of critical importance that will be used to conduct world-class health and medical research.
- The **Frontier Health and Medical Research Initiative**, which provides $700 million over 10 years from 2024–25 and aims to create opportunities to explore bold and innovative ideas, make discoveries of great potential, and to support the translation and commercialisation of these discoveries to achieve global health impact.

The following MRFF grant opportunities are open for application under these Initiatives:

- The 2024 Clinical Trials Activity Grant Opportunity: closes on 2 April 2025. This grant opportunity offers $63 million over 4 years from 2025–26 across 4 streams of funding. It aims to fund clinical trials in two priority areas:
  - Rare cancers, rare diseases, and unmet need
  - Effective health interventions.
- The 2024 International Clinical Trials Collaboration Grant Opportunity: Round 2 closes on 5 February 2025. This grant opportunity offers $6.3 million overs 5 years in this round, to support international collaborations to enhance Australia's capability to lead and collaborate on clinical trial research of global significance and bring benefits to Australian patients.

- The 2022 Frontier Health and Medical Research Grant Opportunity: opened on 13 February 2023, under the Frontier Health and Medical Research Initiative, and is expected to close on the 31 March 2026. Under this grant opportunity:
  - $400 million will be provided over 9 years for ambitious, exploratory and ground-breaking programs of research that deliver treatments for serious and incurable health conditions through a series of linked projects with a maximum investment of $25 million.
  - Applicants can submit an expression of interest any time until the expected close, shortlisted applicants are invited to submit full applications for a project of up to 5 years within the program of research.

Other grant opportunities under the MRFF:

- In addition, grant opportunities under other MRFF Initiatives may also be relevant to your research. For example, grant opportunities under the Genomic Health Futures Mission, the Preventive and Public Health Research Initiative, and the Clinician Researchers Initiative. These grant opportunities may have a specialised focus, but can also fund clinical trial research. All applications will undergo an independent peer review process by a Grant Assessment Committee to be found fundable.
- Explore the MRFF website, including the grant opportunities calendar to identify additional grant opportunities that may be relevant to your research.

Read the Grant Opportunity Guidelines, particularly the objectives of the grant opportunity (Section 1.3) carefully, to support the development of a strong grant application.

The MRFF periodically publishes reports on the operation of the MRFF, analyses of the grants, and reviews of its Initiatives and/or Missions. Relevant publications include:

- Report on Chief Investigator Data (released September 2024)
- MRFF Financial Assistance Report (released May 2023)

Engage with the MRFF

- Register with GrantConnect to stay up to date on current grant opportunities under the MRFF.
- Explore the MRFF forecast calendar for upcoming grant opportunities under the MRFF.

- Nominate yourself to be part of an MRFF Grant Assessment Committee to review grant applications.
- Subscribe to the MRFF fortnightly newsletter to receive up-to-date information on grant opportunities, public consultation processes, reports about the MRFF, and MRFF-led webinars to your inbox.
- Send any questions to mailto:MRFF@health.gov.au

To learn more about MRFF, view the presentation here.

Clinical Trials and Cohort Studies (CTCS) grants programs

There are no updates for the CTCS grants programs. Workshop participants are encouraged to visit the CTCS webpage for information and updates.

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Session 6:
New concepts and ideas

Direct oral anticoagulants prophylaxis for cancer-associated venous thromboembolism using the fibrinogen + D-dimer risk assessment model

Dr James Yeung (Haematologist, SAN Hospital and Visiting Medical Officer, Canterbury Hospital), via video presentation (facilitated by Dr Angelina Tjokrowidjaja)

Direct oral anticoagulants (DOAC) are standard of care treatment for cancer-associated venous thromboembolism (CA-VTE). Prophylaxis for CA-VTE decreases bleeding risk in this high-risk population. Despite recommendations in international guidelines, prophylaxis for CA-VTE is not standard practice in Australia.

TARGET-TP is a phase 3, randomised, multicentre study of participants commencing systemic anticancer therapies for lung or gastrointestinal cancers. Participants were stratified according to their risk assessment based on fibrinogen and d-dimer levels: low-risk (observation) and high-risk (randomised, observation and low-molecular-weight heparin, LMWH) cohorts.

This concept proposes to i) expand TARGET-TP into an unselected cancer patient cohort and ii) use DOAC rather than LMWH to better reflect contemporary practice and improve quality of life.

For updates, information and collaboration opportunities, please email James Yeung at James.Yeung@health.nsw.gov.au.

Democratizing equitable access to cancer trials knowledge through transparent open data sharing and AI-powered annotation: The ARTICANZ initiative

Dr Frank Lin (Medical Oncologist and Biomedical Informatician)

Clinical trial matching can be a time-consuming and manual process. However, with advancements in artificial intelligence (AI), a recent implementation study demonstrated that AI decision support systems may be associated with increased precision of trial recommendations.

The Annotated Registry of Trials in Cancer (Aus/NZ) (ARTICANZ) concept proposes a search engine to allow for efficient searching of all cancer clinical trials. Some features include:

- Recruitment information tracking
- Use of AI to annotate trials, e.g. eligibility criteria, drug class, cancer type

More detail is provided in the presentation here.

For updates, information and collaboration opportunities relating to the ARTICANZ initiative, please email Frank Lin at Frank.Lin@sydney.edu.au.

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Session 7:
New imaging techniques and treatment

Imaging, quantifying and targeting hallmarks of cancer

Dr Ivan Ho Shon (ARTnet Scientific Committee Member and Senior Staff Specialist, Prince of Wales Hospital)

This presentation provided an overview of molecular imaging and therapies with specific concepts to guide potential additional endpoints in molecularly targeted clinical trials within the remit of GCCTI.

For more information, please view the presentation found here, or for collaboration opportunities, please email Ivan Ho Shon at i.hoshon@unsw.edu.au.

Imaging, targeting and amplifying cell death in malignancy

Prof Philip Hogg (Head, ACRF Centenary Cancer Research Centre)

This presentation focused on the cell death hallmark of cancer, specifically, the clinical development of cell death indictor (^{68}Ga-CDI). This molecule only penetrates the membrane of dead/dying cells, and once penetrated, will strongly bind to Hsp90.

Briefly, the clinical development of ^{68}Ga-CDI:

- **First-in-human trial:** n=5, completed in 2022
- **Diagnostic proof-of-concept trial:** Use of CDI-PET to measure response to therapy. Planned for 36 participants with oesophageal/gastro-oesophageal junction carcinoma or rectal cancer, breast cancer, diffuse large B cell lymphoma or grade III follicular lymphoma, across 5 Sydney sites. CDI-PET scan pre- and post-treatment (14 days pre- and 3–8 or 15–20 days post-cancer treatment)
- **Pancreatic cancer trial:** Planned for 96 participants with borderline resectable, locally advanced and metastatic pancreatic ductal adenocarcinoma, across 10 sites.

For more information, including primary results of clinical trials using CDI-PET, please view the presentation found here, or for collaboration opportunities, please email Phil Hogg at Phil.Hogg@sydney.edu.au.

Radiomic analysis of FDG-PET in soft tissue sarcoma

Dr Alex Noh (School of Clinical Medicine, Faculty of Medicine and Health, UNSW)

This presentation showcased a case study involving FDG-PET radiomic analysis to predict survival in patients with soft tissue sarcoma. FDG is a marker of glucose metabolic activity and an indicator for dysregulated cellular metabolism. Increased FDG uptake is correlated with more aggressive tumour cells. Radiomics provides additional information on tumour characteristics such as its shape, heterogeneity and texture.

For more information, please view the presentation found here, or for collaboration opportunities, please email Alex Noh at anoh3355@gmail.com.

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Workshop evaluation

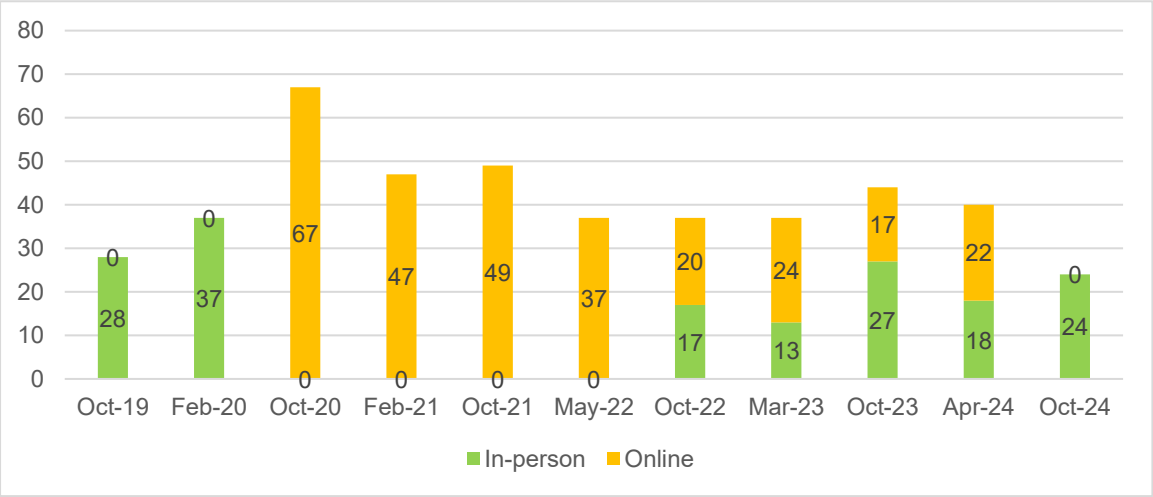
Introduction

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

Participation and survey response rate

Twenty-four participants attended the GCCTI October 2024 workshop.

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



Thirteen of the 24 participants who attended the workshop completed the survey (a 54% response rate), an increase in the response rate from the previous workshop, which was 37.5%.

The majority of survey respondents identified as clinical and academic researchers (61% each), followed by basic scientists (25%).

Organisations/groups in attendance

Participants from organisations/groups across Australia attended.

- Amplificare Pty Ltd
- Cancer Australia
- Centenary Institute, NSW
- Fiona Stanley Hospital, WA
- Garvan Institute of Medical Research, NSW
- National Health and Medical Research Council
- National University Cancer Institute, Singapore
- NHMRC Clinical Trials Centre, NSW
- Peter MacCallum Cancer Centre, VIC
- Prince of Wales Hospital, NSW
- Princess Alexandra Hospital, QLD
- St George Hospital, NSW
- The University of Sydney, NSW
- University of NSW (UNSW), NSW
- University of Newcastle, NSW
- University of Technology (UTS), NSW
- Cancer Cooperative Clinical Trials Groups (CCTGs)
    1. AGITG
    2. ANZSA
    3. ANZCHOG
    4. ANZGOG
    5. ANZUP
    6. BCT
    7. COGNO
    8. PaCCSC & CST
    9. PoCoG
    10. TOGA
    11. TROG

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Understanding the workshop's aim and purpose

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

69% of respondents ‘agreed’, and 31% of respondents ‘strongly agreed’.

Usefulness and relevance of the presentations

100% of respondents indicated that they found the content of the workshop presentations useful and relevant

54% of respondents ‘agreed’, and 46% of respondents ‘strongly agreed’. Respondents noted:

“Stats and methods great”

“Good range with useful practical info sessions”

“Innovation/clinical trial methodology”

“If possible make the concepts age-agnostic. This would align well with the existing focus on molecularly-targeted, disease-agnostic approaches and broaden inclusivity”

Organisation and format of workshop

100% of respondents indicated that the workshop was well organised

46% of respondents ‘agreed’, and 54% of respondents ‘strongly agreed’.

100% of respondents indicated that the in-person only format of the workshop was successful

31% of respondents ‘agreed’, and 69% of respondents ‘strongly agreed’.

“I really value the in-person format. Great for networking and overall engagement”

“Hybrid option still useful for those wanting to join but unable to make in person”

Topics/aspects most interesting/useful

Participants were asked to comment on which workshop topics and aspects they found most interesting. In particular, clinical trial concepts were noted by 38% of participants and imaging was noted by 31% of participants.

Additional comments/suggestions to enhance future workshops

A couple of participants noted the “great discussions” and “collaboration potential” of the workshop. Participants were also asked for suggestions to further improve workshops; the following suggestions were provided:

- More genomic content
- Circulating a list of attendees with agenda prior to workshop

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Appendix: Workshop agenda

Venue Education Room, Chris O'Brien Lifehouse

Time/Date 9.30am – 4.00pm, Friday 25 October 2024

Purpose This Workshop aims to facilitate development of clinical studies based on molecular characterisation that involve cancers from more than one primary site and more than one Cancer Cooperative Trials Groups (CCTGs).

Time	Session	Presenter
9:20am	*Registrations*	
9:30am	**Welcome, introductions, purpose and background of workshop**	*Katrin Sjoquist*
9:40am	**PrOSPeCT and Omico updates** *Chair: John Simes*	*David Thomas*
	• Opportunities and ideas	*All*
10:15am	**Updates from previous workshops** *Chair: John Simes*	
	• OUTRUN-2 • AUTO-CHECK-microbiome • REZOLV3R	*Yu Yang Soon* *Sonia Yip* *Katrin Sjoquist*
11:00am	*Morning Tea*	
11:20am	**Updates from selected CCTGs and groups** *Chair: Katrin Sjoquist*	
	• TROG • PoCoG • ANZUP • ALLG • Opportunities and ideas	*Joe Sia* *Nicci Bartley* *Vinod Subhash* *Delaine Smith* *All*
12:00pm	**Management of brain metastases from multiple cancer types** *Chair: Katrin Sjoquist*	*Yu Yang Soon*
	• Opportunities and ideas	*All*
12:30pm	**Grant updates** *Chair: Martin Stockler*	
	• Cancer Australia: New developments around the relaunch of Priority-driven Collaborative Cancer Research Scheme • Overview of upcoming grants • Q&A/discussion	*Adam Lambert* *Katrin Sjoquist* *All*
1:00pm	*Lunch*	
1:40pm	**New concepts and ideas** *Chair: Martin Stockler*	
	• DOAC prophylaxis for cancer-associated VTE using the fibrinogen + D-dimer risk assessment model • Democratizing equitable access to cancer trials knowledge through transparent open data sharing and AI-powered annotation: The ARTICANZ initiative	*James Yeung/ Angelina Tjokrowidjaja* *Frank Lin*
2:10pm	**Novel imaging techniques and treatment** *Chair: Martin Stockler*	
	• Imaging, quantifying and targeting hallmarks of cancer • Imaging, targeting and amplifying cell death in malignancy • Radiomic analysis of FDG-PET in soft tissue sarcoma • Opportunities and ideas	*Ivan Ho Shon* *Phil Hogg*

		Alex Noh *Panel discussion*
3:25pm	**Progressing ideas** **Reflection, plans, feedback, and advice**	*Katrin Sjoquist* *Group discussion*
3:45pm	**Wrap-up and close**	*Katrin Sjoquist*