



Welcome to the Genomic Cancer Clinical Trials Initiative (GCCTI) update. The GCCTI was established by Cancer Australia in 2013 and is led by the NHMRC Clinical Trials Centre (CTC) in partnership with Zest. The initiative aims to facilitate the development of mutation-specific/molecularly-targeted clinical trial concepts that involve cancers from more than one primary site and more than one national cancer cooperative trials group (CCTG). The main activities of the GCCTI are to develop capacity, ideas, trial concepts, and grant applications.

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Highlights from the October 2024 GCCTI workshop

The GCCTI Project Team hosted a bi-annual workshop on Friday 25 October 2024, with 24 participants attending in-person.

The workshop aimed to provide a forum for Australia's leading cancer researchers, CCTGs, and the GCCTI Scientific Steering Group to discuss and generate ideas and opportunities for studies and grants involving cancers from multiple primary sites and multiple CCTGs.

Presentations and discussion included:

- Updates from funding bodies, previously presented concepts, and CCTGs
- PrOSPeCT and Omico updates
- Management of brain metastases from multiple cancer types
- New imaging techniques and treatment
- Collaboration opportunities involving new concepts and ideas

Further details of the presentations and discussions are available from the [GCCTI website here](#).



Updates on grant opportunities

An update was presented from Cancer Australia (CA) and a written update was provided by the Medical Research Future Fund (MRFF), details are published in the workshop report [here](#). There were no updates to grants from the National Health and Medical Research Council (NHMRC).

Progress updates from previous presented concepts

Updates on concepts presented at previous GCCTI workshops were shared. For further details, please read the workshop report available [here](#).

- 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 OTRUN)
Dr Yu Yang Soon
- 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
- Intraperitoneal bevacizumab for recurrent, malignant ascites (REZOLV3R)
A/Prof Katrin Sjoquist

Updates from selected CCTGs and groups

In supporting the 14 national CCTGs to generate new ideas/concepts involving multiple cancer types and groups, selected CCTGs were invited to share ideas from their group that would have applicability to other cancer types and/or CCTGs. This workshop, ALLG, ANZUP, PoCoG and TROG showcased some of their ideas and concepts. For further details, please read the workshop report available [here](#).

- ALLG – *Ms Delaine Smith (video recording)*
- ANZUP – *Dr Vinod Subhash*
- PoCoG – *Dr Nicci Bartley*
- TROG – *Dr Joe Sia*

Collaboration opportunities involving new concepts and ideas

Three concepts were presented. For updates, information and collaboration opportunities, please contact the presenter/s directly.

- Management of brain metastases from multiple cancer types
Dr Yu Yang Soon – yu.soon@sydney.edu.au
- Direct oral anticoagulants prophylaxis for cancer-associated venous thromboembolism using the fibrinogen + D-dimer risk assessment model (video recording, facilitated by Dr Angelina Tjokrowidjaja)
Dr James Yeung – 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 – frank.lin@sydney.edu.au



New imaging techniques and treatments

This session focussed on molecular imaging and its application across multiple cancer types. For further details, please read the workshop report available [here](#).

- **Imaging, quantifying and targeting hallmarks of cancer** – *Dr Ivan Ho Shon*
Overview of imaging and therapies to guide potential additional endpoints in molecularly targeted clinical trials
 - **Imaging, targeting and amplifying cell death in malignancy** – *Prof Phil Hogg*
A cell death hallmark of cancer, cell death indicator (⁶⁸Ga-CDI) and its clinical development
 - **Radiomic analysis of FDG-PET in soft tissue sarcoma** – *Dr Alex Noh*
Case study predicting survival in patients with soft tissue sarcoma using FDG-PET radiomic analysis
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Update on GCCTI supported studies

EMBRACE

EMBRACE is a phase 2 trial of the poly-adenosine diphosphate-ribose polymerase (PARP) inhibitor, olaparib, in homologous recombination (HR)-deficient metastatic breast and relapsed ovarian cancer in patients without germline mutations in the breast cancer genes BRCA1 or BRCA2. This trial aims to determine the activity of olaparib in 2 cohorts (triple negative breast cancer and high-grade serous ovarian carcinoma) based on objective tumour response rate. Funding for the trial from Cancer Australia was secured in December 2016 in an application led by A/Prof Katrin Sjoquist et al., in collaboration with ANZGOG, BCT, and CTC.

Recruitment to the EMBRACE trial closed 31 March 2022. A total of 22/60 participants were enrolled from 12 sites across Australia. More than 200 patients were screened during the recruitment period. Analyses of trial results and translational substudies are near complete, with additional substudies proposed. A manuscript has been submitted to Molecular Cancer.

For more information about EMBRACE, see the trial summary at [ANZCTR](#) or email embrace@ctc.usyd.edu.au.

AUTO-CHECK

AUTO-CHECK is a translational research study looking at the molecular determinants of autoimmunity and immune adverse events in advanced cancer patients treated with immune checkpoint inhibitors. The **hypothesis** is that an underlying genetic susceptibility to **autoimmunity** increases the risk of an immune-related adverse event (IRAEs) after treatment with immune **checkpoint** inhibitors.

Collaboration with CCTGs: This study was funded in January 2017 by Cancer Australia and is led by Prof Matthew Cook (CIA) and Dr Sonia Yip in a collaboration with the Australasian Lung Cancer Trials Group (ALTG; now known as the Thoracic Oncology Group Australasia (TOGA)), Australia New Zealand Gynaecological Oncology Group (ANZGOG), Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP), Cooperative Trials Group for Neuro-Oncology (COGNO), the CTC, and the Centre for Personalised Immunology at The Australian National University.



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Trials and tumour types: Bio-specimens were collected from 6 multi-centre, investigator-initiated trials of immune checkpoint inhibitors spanning 5 tumour types (endometrial, glioblastoma, mesothelioma, non-small cell lung cancer (NSCLC), renal cell) – each trial using immune checkpoint inhibitors. Biospecimens were also collected from a single centre cohort (Canberra Hospital).

Participants and samples: AUTO-CHECK included 257 participants, and over 450 real-time blood shipments from 48 sites to the central lab in Canberra. Approximately 50 participants had blood samples collected following an IRAE.

Analyses: Serological profiling and whole genome sequencing were completed. Immune profiling of peripheral blood mononuclear cells (PBMCs), genome-wide association study (GWAS) analyses are ongoing in 2025.

There have been multiple conference abstracts and posters at CCTG scientific meetings; and one publication to date (Hao Y *et al.* 2023 *Cell Mol Immunol* doi.org/10.1038/s41423-023-01027-8).

For more information about AUTO-CHECK, please see this [summary](#) or contact autocheck.study@sydney.edu.au.

REZOLV3R

REZOLV3R is a randomised, double-blind, multicentre, phase 3 trial of palliative intraperitoneal bevacizumab following therapeutic ascitic drainage for recurrent, malignant ascites in patients with chemotherapy-resistant solid tumours.

Symptomatic patients with recurrent malignant ascites suitable for paracentesis and a paracentesis-free interval (PFI) of 28 days or less will be randomised 1:1 to a single dose of intraperitoneal bevacizumab or control, following drainage of symptomatic ascites per usual site practice.

The primary objective is to compare time between first and second on study paracentesis, or death (paracentesis free survival time), with secondary objectives including patient-reported outcomes (symptoms, quality of life and supportive care measures), activity measures (numbers and intervals between subsequent paracenteses), overall survival and health economic evaluations (healthcare resource use, health system costs and cost effectiveness)

REZOLV3R is being conducted by CTC in collaboration with GCCTI, ANZGOG, AGITG, and CST.

This trial was funded in 2023 by Cancer Australia in the PdCCRS scheme, with a pilot phase supported through a Program Grant to NHRMC CTC. A/Prof Katrin Sjoquist is leading the trial with Prof Michael Friedlander (co-chair) and Dr Katherine Francis (research fellow).

The protocol received ethics approval in March 2024 and three sites have opened to recruitment with a further two in start-up. Congratulations to Dr Tam Bui and the Concord Repatriation Hospital team for randomising the first patient in December 2024. Site selection continues; please contact the study team to discuss interest or for more information via rezolv3r.study@sydney.edu.au.



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Upcoming events

GCCTI Grant Development Workshop, 28 March 2025



**GCCTI GRANT
DEVELOPMENT
WORKSHOP**

Friday 28 March 2025
**Chris O'Brien Lifehouse,
Camperdown, Sydney**

Click to register
To find out more or to be kept up to date,
please email info@gccti.org.au.

This workshop will provide attendees an opportunity to:

- Learn about current grant opportunities, guidelines, assessment criteria, and recent changes
- Be kept up-to-date with concepts presented previously
- Present synopses of grants you plan to submit for feedback from development groups and your peers*
- Discuss and generate ideas for grants to submit beyond 2025, especially those including multiple cancer types and multiple Cancer Cooperative Trial Groups (CCTGs)

**Proposed grants need not be eligible for GCCTI support*

ANZGOG ASM

Reflections and Projections: Looking Back To Move Forward in Gynaecological Cancer Research

Date/Time: Wednesday 5 March – Friday 7 March 2025

Location: Hyatt Hotel, Canberra

More information: <https://www.anzgog.org.au/inform/annual-scientific-meeting-2/>

Contact: Heshani Nesfield
heshani.nesfield@anzgog.org.au

TROG ASM

Advancing Cancer Care Everywhere: Integrating Inclusiveness and Innovation into Cancer Trials

Date/Time: Tuesday 18 March – Friday 21 March 2025

Location: VOCO Hotel, Brisbane

More information: <https://www.trogasm.com.au/>

Contact: Lianna Danielle Rizk
lianna-danielle.r@asnevents.net.au

PaCCSC/CST Research Forum

The science behind the art of care: Clinical trials in cancer symptoms and palliative care

Date/Time: Thursday 27 March – Friday 28 March 2025

Location: International Convention Centre, Sydney

More information: <https://www.uts.edu.au/research/impacct/paccsc-cst-research-forum-2025>

Contact: cst@uts.edu.au

CQUEST & CREST Quality of Life Workshop

Date/Time: Friday 4 April 2025

Location: CB01 Tower, University of Technology Sydney

More information: <https://www.uts.edu.au/research-and-teaching/our-research/cancer-research-economics-support-team/events/joint-cquest-crest-workshop>

Contact: crest@uts.edu.au



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GCCTI support

The primary aim of GCCTI is to facilitate the development of mutation-specific clinical trial concepts that involve cancers from more than one primary site and across more than one CCTG.

If you'd like to discuss an idea for a cancer clinical trial that includes multiple primary types and/or multiple CCTGs, please complete and submit the [idea generation template](#) and forward it to the GCCTI Project Team at info@gccti.org.au. We look forward to hearing from you.

You can also access a range of information and resources from the GCCTI website: <http://gccti.org.au>.



GCCTI

GET IN TOUCH
info@gccti.org.au

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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