

Genomic Cancer Clinical Trials Initiative December 2019 Newsletter

Welcome to the Genomic Cancer Clinical Trials Initiative (GCCTI) update for December 2019. The GCCTI was established by Cancer Australia in 2013 and is led by the NHMRC Clinical Trials Centre in partnership with Zest. The aim of the initiative is to facilitate the development of clinical trials that involve cancers from multiple primary sites and multiple cancer cooperative trials groups (CTGs). The main activities of the GCCTI are to develop capacity, ideas, and grant applications. Studies developed by the GCCTI that have been successfully funded include EMBRACE, AUTO-CHECK and SEQUITUR.

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Highlights from the October 2019 GCCTI workshop

The GCCTI Project Team in collaboration with the Scientific Steering Group (SSG), hosted a bi-annual GCCTI workshop in October 2019.

The workshop focused on innovative ideas and new concepts including the sharing of studies and ideas between Cancer Clinical Trial Groups (CTGs) relevant to GCCTI and updates and lessons from existing GCCTI supported trials, to support the prioritisation of concepts for grant applications in 2020.

The workshop was attended by 28 participants including researchers, clinicians and CTG representatives.

Presentations and discussion included:

- Overviews of innovative ideas and new concepts which may be developed and considered for future grant applications

- Updates on various CTG studies, in addition to GCCTI supported ideas and trials (EMBRACE, AUTO-CHECK, SEQUITUR)
- Ideas for new areas, molecular targets, and/or drugs for development

The GCCTI Project Team and the SSG would like to thank workshop participants for their time and involvement. The workshop report is available for download on the GCCTI website [here](#). For more information, please contact Natasha Black at Natasha.Black@zest.com.au.

GCCTI 1-day Grant Development Workshop

Save the Date

Date: Friday, 28 February 2020

Time: 9.30am – 3.00pm

Location: Sydney

*Wanting to strengthen the grant application you will submit in 2020?
Interested in discussing and generating ideas for grants to submit beyond 2020?*

GCCTI welcomes you to attend our next workshop on Friday 28 February 2020.

The purpose of this workshop is to provide attendees an opportunity to:

- Learn about current grant opportunities, guidelines, assessment criteria, and recent changes
- Present synopses for grants you will submit in 2020* to receive feedback from mock grant review panels of expert peers
- Learn about current and imminent studies of genomic profiling to guide cancer treatment
- Discuss and generate ideas for grants to submit beyond 2020, especially those including multiple cancer types and multiple cooperative groups

**proposed grants for presentation need not be eligible for GCCTI support*

Further details, including how to register, will be released in the New Year.

Concepts for development

The GCCTI in collaboration with the SSG are seeking to progress the following concepts:

- Exceptional Responders Program
- PIK3CA Paragon 2 – multi basket gynaecological trial

The GCCTI project team will work with interested CTGs and members to explore and strengthen concepts for grant submission. For more information, please get in touch with the GCCTI Chair, Martin Stockler.

Update on GCCTI supported studies

EMBRACE

The EMBRACE study is a Phase II clinical trial of the PARP inhibitor, olaparib, in HR-deficient metastatic breast and relapsed ovarian cancer in patients without germline mutations in BRCA1 and BRCA2. This study is led by Dr Katrin Sjoquist and coordinated by the NHMRC Clinical Trials Centre, in partnership with ANZGOG and BCT.

The aim of this trial is to determine activity of olaparib in each tumour cohort (TNBC and HGSOc) as determined by the objective tumour response rate according to RECIST v1.1.

EMBRACE pre-screening recommenced 17 May 2019 following local RGO approval for an amended protocol to expand the current inclusion criteria with reference to breast cancer, which will assist with screening and recruitment.

There are currently 9/12 active sites since July 2017, with 3 sites to be opened Q3 2019. Since October 2017, 97 patients have completed pre-screening, of which 9 have now been recruited; recruitment is currently planned to end Q3 2020.

For more information about EMBRACE, please visit the [ANZCTR website](#) or contact 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. This study is led by Prof Matthew Cook (CIA) and Dr Sonia Yip and commenced in March 2017.

The hypothesis of this study is that a group of patients with a genetic susceptibility to autoimmunity are more likely to develop an immune related adverse event (IRAEs) after treatment with immune checkpoint inhibitors.

AUTO-CHECK uses data and bio-specimens from 6 multi-site investigator-initiated trials across 4 co-operative trials group (ALTG, ANZGOG, ANZUP and COGNO), with trials spanning 5 tumour types – each trial using immune checkpoint inhibitors.

The first hospital site was activated in June 2017, with 82 (of which 46 unique) sites now activated, an increase from 63 from previously. Recruitment to date as at November 2019 has increased to 84% (253/300) of target participants, from 55% (164/300) in November 2018. Real-time blood shipments from the hospital sites to the ANU central lab have increased from 244 to 436 in the same period, and 47 IRAE blood samples have been collected to date. **Recruitment closes 19 December 2019.**

For more information about AUTO-CHECK, please visit the [GCCTI website](#) or contact autocheck@ctc.usyd.edu.au.

SEQUITUR

Sequential immunotherapy in patients with underserved rare cancers (or SEQUITUR) is a multi-arm platform trial of open-label, multicentre, sequences of Phase II basket trials using hierarchical modelling and borrowing power across multiple cancer types using a master protocol.

The study design includes combination immunotherapy, sequential therapy, adaptive design and a Bayesian cluster hierarchical model. The primary objective of the study is to evaluate the response rate (RR: (CR+PR)) by tumour type, and RR hierarchically across baskets but also survival, duration and depth of response.

The brain cancer section of the trial (SEQUITUR-Brain) is proceeding, and intends to recruit 300 participants from multiple rare brain cancer baskets (e.g. ependymoma, meningioma, rare gliomas) who will be treated with first sequence of an IO combination. Approximately 120 of these participants will subsequently be treated with a second sequence of another IO combination.

An immunotherapy grant for \$500,000 over 3 years has been provided by the Cure Brain Cancer Foundation, with timelines having been extended by 1 year.

For more information about SEQUITUR, please contact Martijn Oostendorp at martijn.oostendorp@ctc.usyd.edu.au.

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 CTG.

If you'd like to discuss an idea for a cancer clinical trial that includes multiple primary types and multiple CTGs, please complete and submit the [idea generation template](#) and forward it to the GCCTI Project Team through Natasha Black at Natasha.Black@zest.com.au.

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

Season's greetings

The GCCTI Project Team would like to thank you for your continued support and collaboration. We wish you a safe and relaxed break over Christmas and New Year, and look forward to working with you in 2020.

For more information about the GCCTI or to organize a meeting with the project team, please get in touch with Natasha Black at Natasha.Black@zest.com.au.



Get in touch
info@zest.com.au

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