Genomic Cancer
Clinical Trials Initiative

GENOMIC CANCER CLINICAL TRIALS INITIATIVE

MARCH 2019 WORKSHOP REPORT

Genomic Cancer Clinical Trials Initiative

Contents

INTRODUCTION

The Genomic Cancer Clinical Trials Initiative (GCCTI) was established in 2013 and is funded by Cancer Australia. The GCCTI is a technical service that aims to support the national cancer cooperative trials groups (CTGs) funded under Cancer Australia's *Support for Cancer Clinical Trials* program to develop **mutation-specific clinical trials concepts** and **grant applications involving cancers from more than one primary site and more than one CTG**.

GCCTI is led by the NHMRC CTC in partnership with ZEST Health Strategies. Scientific and technical input is provided by the NHMRC CTC, with communications, project management and stakeholder engagement undertaken by ZEST Health Strategies.

The GCCTI project team in collaboration with Scientific Steering Group (SSG) held a one-day workshop, at the Stamford Plaza Sydney Airport on **Friday 29th March 2019.**

PURPOSE OF WORKSHOP

The GCCTI annual workshops aim to provide a forum for Australia's leading and emerging cancer researchers, CTGs, and the GCCTI Scientific Steering Group to discuss ideas and opportunities for studies and grants, based on molecular characterisation including two or more tumour types and two or more CTGs.

The March 2019 workshop focused on **preparing for grant submissions in the upcoming 2019 rounds.** This workshop also provided an opportunity for participants to present their developing ideas to gain feedback and advice from mock grant review panels comprised of peers.

As an introduction, the workshop was opened with an overview of GCCTI's aims, objectives and ways to be involved with GCCTI.

The workshop also included a series of presentations from representatives of key funding bodies, to provide updates on the key grant programs in Australia. There were also discussions on the practical aspects of developing a grant; such as the grant review process, addressing assessment criteria, and considerations in the development of budgets and timelines.

The afternoon session involved a group activity, where participants were able to present their developing ideas to gain feedback and advice from their peers in the format of a mock grant review panel.

Further information about the Workshop program is presented in Appendix I

WORKSHOP WELCOME

This session was presented by Professor Martin Stockler (Chair of the GCCTI Scientific Steering Group and project team). The presentation focussed on the purpose of GCCTI as well as the opportunities for engagement with the GCCTI.

The primary aim of the GCCTI is to support the national cancer cooperative trials groups (CTGs) by developing mutation-specific clinical trials concepts and grant applications involving cancers from more than one primary site and more than one CTG.

The scope and key deliverables of the GCCTI from 2018-21 is to:

- Develop at least four mutation-specific clinical trial concepts and/or protocols that involve collaboration with more than one CTG and other key clinicians/groups;
- Submit grant applications for funding of these trials, including preparation of budgets;
- Include quality of life and pharmaco-economic measures, where applicable (to be developed collaboratively with the Cancer Australia Chair in Quality of Life and Health Economics Service;
- Host an annual workshop with all CTGs and key stakeholders to identify potential targets for the development of mutation-specific cancer clinical trial protocols.

The additional outcomes and benefits as a result of the GCCTI were also highlighted. This includes:

- **Molecularly-focused networks** of researchers, clinicians and scientists
- **Increased capacity** for the conduct of genomic cancer clinical research
- **Strategies for managing challenges** associated with trials of targeted treatments
- **Structures to support conduct** of trials that include multiple primary sites and multiple cooperative trials groups

Participants were encouraged to be involved with the GCCTI through various means, including:

- Developing and submitting concepts/ideas to GCCTI
- Contributing to idea generation and prioritisation through attendance at the annual workshop
- Providing input into grant applications through joining GCCTI supported grant development teams.

A brief overview and update of the GCCTI supported trials and studies (EMBRACE, AUTO-CHECK and SEQUITUR) was also provided.

UPDATE ON NEW NHMRC AND MRFF GRANTS PROGRAMS

This session was presented by Adjunct Professor Davina Ghersi from the National Health and Medical Research Council (NHMRC). The presentation focussed on key changes to the new NHMRC Grants Program, as well as an overview of the Medical Research Future Fund (MRFF), as supported by the NHMRC.

NHMRC GRANTS PROGRAM

The focus of this presentation was on the NHMRC Clinical Trials and Cohort Studies Grants. The aim of these grants was reiterated as 'supporting high-quality clinical trials and cohort studies that address important gaps in knowledge, leading to relevant and implementable findings for the benefit of human health'.

It was noted that the Clinical Trials and Cohort Studies Grants were considered as a separate scheme, and that the number of grants that could be applied for and held was not capped.

Grant Connect and Sapphire

Workshop participants were encouraged to visit the Grant Connect website to download key documents for review prior to commencing proposal development. Grant Connect is the Australian Government's grants information system, which publishes current and forecasted grant opportunities and awards.

Key documents highlighted for review, included:

- Clinical Trials and Cohort Studies Grants 2019 Guidelines
- Clinical Trials and Cohort Studies Grants 2019 – Guide to applicants on preparing an application (which includes category descriptors)

It was also noted that the NHMRC was in the process of developing Sapphire, which is a grants management solution that will replace the current Research Grants Management System (RGMS). It was confirmed that Sapphire was a future focussed solution, and would unlikely be in use for 2019.

Assessment of proposals

An overview of the weighting applied to the key assessment areas of proposals was discussed. This includes:

- Significance (40%)
- Research Quality (40%)
- Team Quality and Capability (20%)

Category descriptors

Workshop participants were strongly encouraged to familiarise themselves with the category descriptors, early in the process of preparing an application. Category descriptors form the criteria applied by the Grant Review Panel, and inform a key part of the assessment.

An overview of the criteria applied under each respective category description was highlighted.

Key discussion points included:

- Recognition of the increased assessment weighting on the significance of a trial. This was discussed as an assessment of whether conduct of the trial would add to new knowledge and contribute to improved health outcomes.
- Suggestions to highlight the quality of the proposed research included provision of a robust sample size, as well as an explanation on how this was achieved (i.e. sample size calculation) and detailed justification of assumptions.
- The inclusion of a systematic review to demonstrate the significance of the proposed research was noted as an ideal, which inclusion of how the systematic review was completed, and reference to how this information has informed the subsequent proposed methodology or trial design.
- References to researchers having reviewed relevant clinical trials registries to ensure that their proposal is novel, and does not duplicate current research studies.
- Ensuring that a diverse representation of individuals are included in the research team, including but not limited to, involvement of early to mid-career researchers, diverse gender representation, and Aboriginal and Torres Strait Islanders.
- Engagement with relevant population groups should be indicated, such as Aboriginal and Torres Strait Islander peoples, with their involvement to reflect the relevant ethical guidelines.
- The expected end users of the results of the study should be articulated, including demonstration of the relevance of the proposed research question to end users. This includes showing how consultation with proposed end users has occurred in the process of trial design, and potential future involvement in the trial's governance bodies.
- Proposed key performance indicators should be realistic, and include recruitment targets and approvals. This is important to support NHMRC in its oversight role of the trial's progress, and to work with researchers to identify risks and implement mitigation strategies early to encourage success of the trial.
- Confirmation that applicants would no longer be provided the opportunity to respond to peer review comments. It was noted that there would also be a reduction in the number of external reviewers. This revised process was introduced to expedite the process for review and assessment, in the context of NHMRC's available resources.
- Mechanistic studies and the relevant grants scheme that would be appropriate for submission was also discussed. It was noted that applicants should review the objectives of the relevant schemes, including the category descriptors and make a

judgement on which scheme may be most relevant (e.g. clinical trials and cohort studies, ideas grants).

Workshop participants were also encouraged to volunteer to participate on grant review panels to gain personal experience on the review process.

The presentation also made reference to useful documents that may support applicants in developing their response. These are presented in the Useful Documents list at the end of this report.

MRFF GRANTS PROGRAM

A brief overview of NHMRC's role in the context of the MRFF Grants Program was also provided. It was acknowledged that the MRFF Grants Program is administered by NHMRC on behalf of the Commonwealth Department of Health (the Department).

The assessment criteria used in the review of applications to MRFF was noted to align with NHMRC's established approaches.

It was reiterated that applicants should consider their application in the context of being able to meet the desired outcomes of the program, and apply accordingly. Workshop participants were encouraged to register with Grant Connect to receive updates on MRFF Programs.

UPDATE ON CANCER AUSTRALIA GRANTS

This session was presented by Dr Gayle Jones from Cancer Australia. The presentation focussed on the Priority-driven Collaborative Cancer Research Scheme (PdCCRS).

PRIORITY-DRIVEN COLLABORATIVE CANCER RESEARCH SCHEME (PDCCRS)

As Cancer Australia's annual national research grants funding scheme, the PdCCRS is designed to collaboratively fund cancer research projects in areas of identified priority. This collaborative approach to grant provision seeks to coordinate, co-fund and maximise the number of Australian cancer research grants funded, as well as avoid potential duplication of funded research in Australia.

Workshop participants were encouraged to download the full details of the PdCCRS through Grant Connect and the Cancer Australia website.

Key discussion points included:

- Confirmation of the PdCCRS Research Priorities – general cancers and childhood cancers of low survival. Each research priority area has unique funding partners, with more details about each area available through Grant Connect and the Cancer Australia website.
- Discussion on the two research categories which can be applied for under the respective research priorities – Standard Grants (Category A) and Early Career

Researcher Grants (Categories B-D). Workshop participants were encouraged to review the specific applicant criteria under each of the respective categories.

- Confirmation of the alignment to the NHMRC Ideas or Clinical Trials and Cohort Studies grant schemes in the assessment of the grant application to PdCCRS and application process.
- Standard Grants (Category A) were confirmed as being able to be submitted through either the NHMRC Ideas or Clinical Trials and Cohort Studies grant schemes.
- Early Career Researcher Grants (Categories B – D) were confirmed as only being accepted through the NHMRC Ideas grant schemes, and that the corresponding NHMRC application should not be more than 3 years in duration.
- Applicants are encouraged to assess which scheme would be most appropriate for submission of their grant proposals; reviewing the specific category descriptors for each scheme to inform their decision.
- Cancer Australia does not make publically available the category descriptors which guide their assessment, with their review and assessment addressing only those responses relating to Cancer Australia's questions (i.e. the application is not reviewed in its entirety).
- Recognition that consumer input is a mandatory requirement as part of the submission to PdCCRS.

An overview of the PdCCRS scoring was given, including the total percentage to which NHMRC GRP scores would contribute. An overview of this is provided in the table below.

		NHMRC GRP Scores	**PdCCRS GRC Scores**
PdCCRS Standard Grants (Category A)	Ideas Grants	40% PdCCRS total	60% PdCCRS total
	Clinical Trials and Cohort Studies	40% PdCCRS total	60% PdCCRS total
PdCCRS Early Career Researcher Grants (Category B – D)	Ideas Grants	50% PdCCRS total	50% PdCCRS total

PREPARING GRANT APPLICATIONS

This session included a series of presentations to support applicants in their approach to preparing grant applications.

UNPACKING THE GRANT REVIEW PROCESS

This presentation was provided by Dr Nik Zeps, discussing his experience as a reviewer on NHMRC Grant Panels.

It was reiterated that the grant review process is undertaken by peers, and that the opportunity exists to find out more about the process through participating in a panel. The importance of referring to the category descriptors for the relevant scheme was also noted.

Key discussion points included:

- Emphasis on the need to write clearly and succinctly so that a clear purpose can be identified.
- Reviewing applications prior to submission to ensure there are no obvious mistakes. Examples of this include correct referencing; ensuring that citations are correct and that any publications which are relevant to the field of research which would be widely known in the community are referenced appropriately.
- To review the aims of a study, in order to minimise the number of dependencies on the initial study's aim being met before the balance of the study's aims are achieved.
- Engaging people outside of the respective field to read the grant application prior to submission, to ensure clarity, logic and understanding of the application to non-subject matter experts.
- Ensuring that consumer input is meaningful, and that there is clear evidence of how they have been engaged either in the grant development process, or through potential continued involvement through the study's governance structures.
- Being clear and pragmatic about the likely knowledge gain or translation of research outcomes that would truly be achieved through the successful completion of your research, if funded.

ADDRESSING ASSESSMENT CRITERIA

This presentation was provided by Associate Professor Mustafa Khasraw, and discussed approaches to addressing the assessment criteria when developing grant applications.

Key discussion points included:

- Ensuring that the aim and purpose of the study is specific and clearly articulated. This includes highlighting the background research undertaken to support the study, including any preliminary or proof of concept studies that have been completed.

- Following the guidance provided for formatting, budgets, and timeframes. This includes providing adequate time for a proof and edit of the application prior to submission.
- Recognition that grant application development can take time, and that it is important to plan at least 6 – 12 months ahead.
- Discussion around the category descriptors and ensuring that applicants are familiar with what is included in the criteria to ensure that these are addressed in a clear, succinct, and convincing manner.

BUDGETS AND TIMELINES

This presentation was provided by Kate Wilson, and focussed on considerations in the preparation of budgets and timelines for a grant application.

Key discussion points included:

- Liaising with the administering research office (if affiliated with a university) and being aware of the internal review process and timelines, if relevant.
- Discussion of the requirements for the preparation of a grant budget, including overview of the costs associated with research facilities, direct research costs (DRC) and equipment, and the research team.
- Reiteration of the importance of justifying the requested duration of study and the associated budget. This includes ensuring that all costs, including the requested Personnel Support Packages (PSP) allocations are correct and reasonable.
- Group discussion on funding allocations for internationally based researchers in the research team. It was confirmed that the funding received through NHMRC should fund Australian based positions only, with experiences from the group about international collaboration shared on how best to address this.

MOCK GRANT REVIEW PANELS (GRP)

This session was facilitated as a group discussion, where attendees were provided the opportunity to present their grant proposals (through a one-page synopsis) to panels comprised of other attendees for discussion and feedback.

There was robust discussion and feedback provided to those who presented their one-page synopsis. Key questions that attendees were asked to consider when presented with the concepts included:

- Which aspects of the proposal were not adequately covered?
- What were the major strengths of the proposal?
- What were the major limitations?
- Is there a sample size justification
- How are the main biases proposed to be mitigated?
- How feasible is the proposed study?
- What is the track record of the members of the research team?

FINAL WORKSHOP DISCUSSION

The workshop concluded with a group feedback session, facilitated by Martin Stocker on participants' thoughts on which aspects of the workshop went well, and how the workshop could be improved in the future.

Overall, positive comments were received about the workshop, with some participants suggesting that the Mock GRP session could be more structured in future. This could be through the provision of guidance on the time available to present, in addition to a document template outlining the key components of the one-page synopsis. Feedback was also provided on being able to extend the duration of the Mock GRP session in the future, supported by participants being provided the synopses to be presented on the day as part of the pre-workshop documentation.

Martin also canvassed the group's feedback on the intention for GCCTI to work in partnership with ACORD to host a multi-day workshop in the October/November 2019 period on grant proposal development. This was generally well received.

Additional feedback on the workshop was also obtained through workshop evaluation forms, with the results presented in the following section.

WORKSHOP EVALUATION

Twenty-six participants attended the GCCTI March Workshop 2019, representing the following groups/organisations:

- GCCTI project team
- GCCTI Scientific Steering Group (SSG)
- CTGs (ASSG/ANZSA*, ALLG, ALTG, ANZCHOG, AGITG, BCT, COGNO, PaCCSC/CST, PC4, MASC**Trials Ltd)
- Cancer Australia
- National Health and Medical Research Council (NHMRC)

*Australia and New Zealand Sarcoma Association Limited
**MASC Trials Ltd. (Melanoma and Skin Cancer Trials Limited) – formerly known as ANZMTG

Workshop participants were encouraged to complete a post-workshop evaluation form, with 18 responses received (69%). The majority of the responders were clinical researchers and representatives of the CTGs.

WORKSHOP EXPERIENCE

Understanding of the aim and purpose
94% of the respondents had a clear understanding of the aims and purpose of the workshop, (82% of the participants agreed and 18% strongly agreed). Only 6% disagreed.

- The workshop was described by one participant as an "*extremely useful exercise"*
- Receiving the agenda beforehand was described by one participant as helpful in supporting an understanding of the workshop's aim.

Effectiveness of the presentations
Similarly, 94% of the respondents found the content of the workshop presentations as useful and relevant (59% respondents agreed and 41% strongly agreed). Only 6% disagreed.

- Referring to the presentations and the mock review panel one respondent said "*it was great to hear about the new grants process… highly valuable feedback was received from the mock review panel"*
- Other respondents found the presentations as useful updates on the grants process by credible presenters
- One of the respondent suggested circulating the presentation slides after the workshop.

General feedback received about the workshop included:

"Valuable, useful, enjoyable! Would love to attend again"… "great workshop, thank you"

ORGANISATION OF THE WORKSHOP

Workshop participants were provided the opportunity to describe what they felt were the most interesting or useful topics or aspects of the workshop.

Around 94% of the respondents found the workshop as well organised, with 6% in disagreement.

- One of the respondent commented "*excellent team"*
- Another participant suggested that providing a synopsis before the workshop would have been helpful in understanding the review process.

A large number of respondents found the first session of the workshop as most useful. The majority of respondents described the presentations from highly experienced and senior NHMRC and Cancer Australia people/researchers as insightful, particularly, around the following areas:

- Grant scoring process
- Focusing on the criteria
- Reviewing good examples of grant submissions
- Understanding the viewpoints of the grant agencies and the reviewers regarding funding applications
- Receiving an update regarding the new NHMRC grants scheme and MRFF funding.

One respondent mentioned, "*Davina's presentation was insightful, the experience of the panel was excellent - picking at the big issues, high level analysis"*

Some of the respondents described the mock review panel as the most interesting aspect of the workshop, including the expert feedback and multi-disciplinary views of the panel reviewers such as Nik Zeps.

Additional suggestions and comments for future workshops included:

- Additional focus around aspects of successful and unsuccessful grant applications, including presentation of examples to assist process for those entering the grant writing phase
- Reducing the overlap between presentations regarding the grants process
- Holding this workshop in the first or second quarter of the financial year to allow further development for grant submission in the fourth quarter, as the timings were very close to the NHMRC deadlines
- Increasing the length of the workshop to allow for increased time to pitch ideas. This could also encourage more interactions between participants (for example, basic scientists and clinicians), or through 'scientific speed dating'.
- Providing a structure/template for presenters beforehand to maximise presentations and feedback opportunities and circulating the concepts which were being presented (prior to the workshop).
- Specification on the workshop's target audience, such as new/junior researchers.

USEFUL DOCUMENTS

The following list outlines documents referenced within the presentations that may be useful in supporting the preparation of grant applications.

- Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) http://www.prisma-statement.org/
- STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) https://www.strobe-statement.org/index.php?id=strobe-home
- Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) http://www.spirit-statement.org/
- NHMRC's Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders 2018 https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples
- NHMRC. Guidelines for Guidelines: Consumer involvement. https://www.nhmrc.gov.au/guidelinesforguidelines/plan/consumer-involvement Last updated 23/11/2018.

APPENDIX I – WORKSHOP AGENDA

GENOMIC CANCER CLINICAL TRIALS INITIATIVE[1]

Workshop 2
AGENDA

Title: Annual Workshop

Venue: **Stamford Plaza Sydney Airport, Cnr O'Riordan St &, Robey St, Mascot NSW 2020**

Details: Friday, 29th March 2019, 9.30am – 3.30pm

Purpose: The March workshop will focus on preparing for grant submissions in the upcoming 2019 rounds. The workshop will provide attendees with the opportunity to present their developing ideas and gain feedback, advice, from mock grant review panels comprised of peers.

Time	Item	Presenter
9.15–9.30am	*Arrivals and registration*	
9.30–9.40am	**Welcome and introductions**	Rob Sutherland
9.40–10.00am	**Overview of GCCTI and achievements to date**	Martin Stockler
10.00 – 10.40am	**Update on new NHMRC Grants Programs**	Davina Ghersi
10.40 – 11.00am	**Update on MRFF Grants Programs**	Davina Ghersi
11.00 –11.30am	*Morning tea*	
11.30 – 12:30pm	**Update on Cancer Australia Grants**	Gayle Jones
	Preparing Grant Applications	
	Unpacking the Grant Review Process	Nik Zeps
	Addressing assessment criteria	Martin Stockler/Mustafa Khasraw
	Budgets and Timelines	Kate Wilson
12.30-1.15pm	*Lunch*	
1:15 – 2:45pm	**Mock Grant Review Panels (GRP)** *Attendees present their grant proposals to panels of about 8 peers according to the standard NHMRC processes. Each proposal allocated 15 minutes for presentation, discussion and feedback.*	Small Groups
2:45 – 3:15pm	**Group report back** *Group feedback and discussion on Mock GRP.*	Facilitator
3.15 –3.30pm	**Wrap-up and Close**	Martin Stockler

[1] 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 Health Strategies.