

Outsmarting cancer, together

Annual Report 2020







About us

We are a unique network of Australia's leading cancer research institutions and hospitals.

Our vision

As a not-for-profit organisation our vision is "to improve outcomes for Australians with cancer by accelerating the use of precision oncology as a research-led model of care, growing the clinical trials industry and modernising the Australian healthcare system."

Our values

innovation, collaboration, hope

We actively encourage and engage in innovation.

Our collaboration and engagement with our community, members and industry makes a difference.

We take responsibility for the quality and effective delivery of our programs.

We act with integrity and compassion to fight for equity of access and bring hope to patients.

Strategic goals

Omico will improve outcomes for Australians with cancer by accelerating the use of precision oncology as a research-led model of care, growing the clinical trials industry and modernizing the Australian healthcare system.

Omico aims to:

- · Improve outcomes for cancer patients
- Fuel cancer research across the Australian cancer ecosystem
- Accelerate collaborations with local and global stakeholders
- Serve as trusted advisors and scientific experts in precision oncology
- Become a leader for precision oncology in the APAC region.

We put patients first

Our mission

Molecular screening & therapeutics

Health system reform



Using heritable genetic information to assess cancer predisposition and investigate clinical risk management.

Supporting patients and families today and planning the health system for tomorrow.



Our board



Mr Paul Jeans

Chancellor, University of

of (Deputy Cl



Mr Richard Vines

(Deputy Chair)*



Professor David Thomas (CEO)*



Emeritus Professor Mark Wainwright AM



Professor Chris Goodnow (Garvan Institute of Medical Research)



Mr Bruce Goodwin (for Medicines Australia)*



Professor John Simes (for University of Sydney)



Professor Kathryn North AO (for Australian Genomic Health



Professor Michael Brown (Member representative)



Professor Ricky Johnstone (Member representative)



Ms Tze Masters*



A/Professor Paul Martin (Company Secretary)

*Finance, Risk and Audit Committee members, Mr Bruce Goodwin is chair of the committee

Our leadership team



Professor David Thomas

CEO



Kelly Constable Chief Strategy Officer



PA16

Deputy CEO



Mr Satish Nair

CFO



Dr Mandy Ballinger Head of Cohorts



Dr Lucille Sebastian Program Manager





Our member network



Omico members see more than 20,000 new cancer patients each year, almost 10,000 of whom have rare or less common cancers. Participating research institutions, with a collective research workforce of more than 1,500 basic and clinical researchers, provide access to internationally competitive basic research programs that facilitate and accelerate the translation of basic discoveries into the clinic.

Our governance



Australian Genomic Cancer Medicine Centre Ltd, trading as Omico, is a not for profit company limited by guarantee.

As a not for profit company with a beneficial purpose, we are regulated by the Australian Charities and Notfor-profits Commission (ACNC).

A not for profit company, limited by guarantee

The Objectives of Omico are to:

- expand the Molecular Screening and Therapeutics (MoST) and Cancer Risk in the Young (RisC and SMOC+) Programs;
- expand the MoST study so as to provide genomic testing and access to collaborative clinical trials for Australians with advanced, incurable, rare and less common cancers across Australian centres of excellence in cancer research and treatment;
- 3. provide a framework for standardised consent,

biobanking of tumour material and genomic profiling;

- 4. make biobanked material available for further research;
- support the collection, maintainence and access to clinical data via national, linked rare cancer registries;
- promote a managed, cooperative and networked approach nationally to research and education between cancer centres so as to maximise the benefits from that research;
- promote and encourage science in Australia through active engagement of members and participants to ensure that the performance of Omico will be greater than that of each member and participant acting independently;
- promote the building of clinical trials capacity nationally through engagement with clinical trials industry (diagnostic imaging, pharmaceutical, biotech and contract research organisations) and the Pharmaceutical Benefits Advisory Committee;
- develop a consumer-led and collaborative approach to professional and community education in the field of rare and less common cancers to maximise translation of the benefits arising from that research;

- 10. develop and utilise Omico intellectual property and resources in order to maximise national benefit, including the Australian biotechnology and pharmaceutical industry and the Australian economy generally; and
- Committees

Program Steering Committee (PSC)

Role: To define the strategic direction of the Program

Chaired by David Thomas (CEO)

Membership includes: Leadership team, Chair of Informatics, Director NHMRC Clinical Trials Centre, Site Principal Investigators, Working group leads, Rare Cancers Data Portal lead, Rare Cancers Australia lead.

PSC Executive Group (PSCEG)

Role: Provide operational oversight and approval of design, development, execution, analysis and reporting of the Program.

Chaired by David Thomas (CEO)

 secure funding for Omico activitites on behalf of the members and participants for the purposes of creating, developing and maintaining social, scientific and research knowledge and capacity, especially in the field of rare and less common cancers.

Membership includes: Leadership team, Business Development, Chair of Informatics, Translational Oncology Laboratory, Cancer Diagnostics, Rare Cancers Australia lead

Clinical Trials (CTWG)

Role: To provide expert advice and assistance on clinical and scientific aspects of the MoST Program, provide recommendations and guidance on the conduct of the MoST Program to the Program Steering Committee Executive Group. To facilitate the development of new research, ongoing oversight and trouble-shooting (as required or escalation) of sub-studies and act as a conduit for communications between and within members.

Co-Chaired by David Thomas (CEO) and John Simes (Director of NHMRC Clinical Trials Centre).



Early Detection and Risk (EDRWG)

Role: To investigate and understand further the heritable drivers of cancer. To use this information to develop interventional programs involving clinical genetics, genetic counselling, radiology/imaging, genomics and bioinformatics to improve outcomes.

Co-Chaired by Mandy Ballinger (Garvan) and David Thomas (CEO)

Molecular Pathology

Role: To review molecular screening results and variant classifications; To coordinate and champion harmonisation of member quality control and assurance monitoring across the nation, and contribute to national genomic strategy.

Co-Chaired by Stephen Fox (Director Pathology, PeterMac) Hamish Scott (Centre for Cancer Biology, SA).

Patient Advocacy and Support

Role: To provide a consumer voice for advocacy, patient information, fundraising, psychosocial support, ethics, legal issues and in dealings with regulatory authorities

Chaired by Richard Vines

Data Curation, Integration and Linkage

Role: To develop the Australian Rare Cancers Data Portal and integration with clinical information and molecular screening. To interface with international community (eg International Rare Cancers Initiative, NCI data commons).

Chaired by Clare Scott (WEHI)

	Number of meetings eligible to attend	Number attended
Mark Wainwright (Chair - resigned 20 May 2020)	5	5
Richard Vines (Deputy Chair)	5	5
Chris Goodnow	5	3
Bruce Goodwin	5	5
Paul Jeans (Chair - appointed 20 May 2020)	5	5
Kathryn North	5	3
John Simes	5	5
Ricky Johnstone	5	5
Michael Brown	5	3
Tze Masters (appointed 10 Sept 2019)	4	4
David Thomas	5	5
In attendance:		
Vera Terry	5	5
Satish Nair	2	2
Paul Martin	5	5

Meetings of Directors

Report from the Chair of the Board and the CEO

To put it mildly, 2020 has been an extraordinary year for all Australians. Through its engagement with the pharmaceutical sector and health care system in every state and territory, the Australian Genomic Cancer Medicine Centre has borne upon the COVID-19 tide. We are pleased to report that COVID-19 has had a relatively small impact on the program, partly due to the high priority our member sites have placed on the value the program brings to their patients. There is much to report.

In May of this year the AGCMC rebranded itself as Omico. This was in response to feedback about the complexity of the old acronym, and a desire to convey the spirit of collegiality, collaboration and co-operation in the genomic space that Omico represents. We think you will agree that the website communicates these messages very well.

This year has seen the completion of the national roll-out of sites, with Princess Alexandra Hospital becoming the last site to activate the Molecular Screening and Therapeutics (MoST) study, meaning that Australians have access to the program in every state and territory. Patient enrolment continues to exceed our original expectations, and we have just passed 2,800 individuals with advanced cancer who have been consented to molecular screening. Over 200 individuals have gone onto one of the 5 therapeutic substudies which have opened since the inception of MoST in late 2016. We are on track to meet our Commonwealth milestones, although we have a short-term need to accelerate opening of new substudies. At the time of writing, more than 400 patients' worth of substudies are in progress.

This year has also seen the establishment of the Long-Term Follow up Unit (LTFU), under Dr Sam Oakes. The LTFU will play a key role in measuring the impact of MoST on clinical outcomes. In promising but early data, those who receive a matched targeted therapy appear to experience a significant prolongation of survival compared to those who did not receive matched targeted therapy. Working out why this is the case, and how to increase the number of options to our patients is a key priority for 2020/21.

Similarly, the Cancer Risk in the Young Study (RisC) and Surveillance in Multiorgan Cancer syndromes studies (SMOC+) have continued to enrol patients throughout the country. More than 1,000 participants have now enrolled onto RisC, and more than 90 onto SMOC+. The SMOC+ program has identified curable cancers in 1 in 4 people being screened with wholebody MRI, which is 10 times the rate at which breast MRI identifies cancers in women at high risk of breast cancer. Breast MRI is currently funded through the MBS for this purpose.

This year has also witnessed two new cancer-specific subprograms, which have built upon the broad framework of MoST. The ASPiRATION study, which aims to enrol 1,000 people with newly diagnosed advanced lung cancer, is a joint project with the Australian Lung Trials Group and Roche. ASPiRATION aims to determine the value of comprehensive genomic profiling in patient outcomes, and is being led by Dr Nick Pavlakis at Royal North Shore and Dr Ben Solomon at Peter Mac. The MoST-LLy program focused on hematologic cancers, and with the support of the Leukemia Foundation of Australia aims to test the MoST model for patients with advanced incurable lymphomas. It is being led from Steven Lane at Queensland Institute of Medical Research, and Hamish Scott at SA Health Pathology.

Omico aims to tackle the hard problems in precision oncology. Of the most common cancer types seen through MoST, lung, pancreas, brain, sarcomas and carcinomas of unknown primary site constitute a major fraction of the biggest killers in our society. Omico has been very successful in developing industry partnerships that bring important new drugs to these patients, but also to source additional funding to enable the program to extend its reach to more Australians. This model of industry-public partnerships, driven by science and patient interest, is important to accelerating advances into the clinic, and to the sustainable future of medicine generally.

All of these successes have been achieved while maintaining a healthy balance sheet, which has enabled us to stretch our initial targets, with a view to addressing the enormous demand from cancer patients and their doctors.

Omico is undergoing a major strategic review process at the board level, as we near the end of the 2nd year in our initial 5-year plan. This process is intended to determine our goals for the next 5 years, and how we get there. We are pleased with the degree of engagement and progress, and will have more to report in coming months. Importantly, the national Oncology Alliance, led by Rare Cancers Australia through Richard and Kate Vines, provides a long-term framework within which Omico hopes to contribute to better cancer outcomes out to 2030.

Finally, Professor Mark Wainwright, the inaugural Chair of the Omico board, announced his intention to formally step down from that position in May, and will retire from the board by the end of this year. Paul Jeans was unanimously elected to replace Mark as the second Chair of Omico. We would like to gratefully acknowledge the major part Mark has played over the past 3 years in getting Omico safely from the draughtboard to a functioning company which is delivering the outcomes promised to the Australian community in 2018. His wise counsel and infallible good sense has been critical to the successes we reported above.

To end where we started, COVID-19 may actually accelerate innovation in the precision oncology space, by enhancing Australia as an attractive space to conduct trials. Thanks to the successes to date, Omico is well-placed to contribute to this activity. As we move into 2021, we expect wonderful new opportunities to develop further exciting programs, through leadership and engagement with our member networks and a broad range of stakeholders from industry, governments and the community.

Mr Paul Jeans (Chair of the Omico Board) Professor David Thomas (CEO)

Research Highlights

The goal of precision oncology is to deliver the right treatment to the right patient at the right dose and the right time.

The Human Genome Project, launched in 1990, helped bring the early concepts of personalised medicine into focus by exploring genetic links to health, where genes, or sets of genes, were discovered to be switched "on" or "of" in patients with disease or cancer.

Molecular screening looks for changes in the genetic information or proteins of tumour tissue or blood cancer cells. Screening tools, including gene panels for taregted sequencing, have entered clinical practice, driven by increasing demand, capacity, and reduced costs.

Molecular sequencing and clinical information is

brought together in the field of clinical genomics where genome sequencing is used to inform patient diagnosis and care.

The current focus for clinical genomics is:

- characterising and diagnosing rare and inherited disease (with the potential in the longer term to apply to common diseases)
- classifying cancer tumours to guide treatment, and
- providing information about an individual's risk of developing disease or their likely response to different treatments.

Molecular profiliing for cancer patients may lead to better prevention, diagnosis, treatment and monitoring.

Molecular Screening and Therapeutics Program (MoST)



Using molecular profiling to find biomarkers to guide therapy options

The purpose of the MoST program is to see if our process of screening or testing tumour tissue for DNA or protein markers identifies a biomarker that can be used to guide treatment. This means that for each enrolled patient we try to find a biomarker (molecular screening) and then, if a suitable biomarker is found, we try to find a therapy matched to that biomarker. The MoST Program is about to enter into its 5th year of operation. Over that time, the Program has developed from a proof-of-concept screening and trials combination run in NSW, to a national program delivered through a network of leading cancer treatment and research centres, encompassing every state and territory in Australia.

The first nine months of 2020 have provided us with major challenges, but as ever, also highlighted a number of opportunities.

Recruitment to the screening component of the Molecular Screening and Therapeutics (MoST) program has been relatively stable and still exceeding expectations.

A highlight of 2020 has been the expansion of the MoST screening platform to accommodate histopathology specific cancer groupings. Areas of expansion have included blood and lung cancers.

Expanding to develop subprograms in blood and lung cancer

Lung cancer kills more Australians than any other cancer, with the majority of people presenting with late-stage incurable disease. In the past decade, development of targeted therapies to specific genomic alterations in metastatic non-squamous non-small cell lung cancer (mNSCLC) represent a major advance in treatment for this disease.

ASPIRATION is a national multi-centre prospective observational and interventional cohort study that aims to investigate the clinical impact of comprehensive genomic profiling (CGP) on the management of metastatic non-squamous nonsmall cell lung cancer (mNSCLC) and assess the feasibility of CGP implementation nationally. The ASPIRATION study leverages the support of the federal government in collaboration with industry and a lung cancer trials group. The collaboration will see 1000 newly diagnosed lung cancer patients being given comprehensive genomic profiling and standard of care testing, with more than 100 eligible patients enrolled onto substudies to test emerging treatments. ASPIRATION will start recruiting patients from January 2021.

Blood cancers are among the most common and lethal cancers in Australia, with about 7000 deaths per year and a peak in young patients. High risk blood cancers such as aggressive lymphoma or leukaemia usually respond to chemotherapy at initial diagnosis. However, relapsed or refractory disease is associated with chemotherapy resistance and this invariably leads to poor outcomes for patients with most studies showing survival of relapsed/ refractory acute myeloid leukaemia/ acute lymphoblastic leukaemia/diffuse large B-cell lymphoma approximately 10-20% at 2 years.

The Leukaemia Foundation and Tour de Cure are supporting the MoST-LLy pilot that will provide molecular screening for up to 240 leukaemia or lymphoma patients and access to innovative clinical trials for up to 32 of those patients. MoST-LLy will start recruiting patients in 2021.



MoST screening update



Treatment recommendations have been made to 1450 patients.

Note:

Patients can have more than one recommendation and can be counted in more than one Tier category. Treatment recommendations fall into 3 categories:

Tier 1 - evidence of tumour mutations that render the patient suitable for treatment in a MoST sub-study,

Tiers 2a and 2b- evidence of tumour mutations for which an existing funded or unfunded drug is available

Tier 3 - evidence of tumour mutations that render the patient suitable for an existing clinical trial outside of MoST sub-studies

MoST therapeutics update



The NHMRC CTC continues to coordinate the substudy development pipeline, collaborating with specialists from the 3 sub-program groups (pancancer, blood cancer and lung cancer) to develop clinical trial concepts. clinical trial methodology, translational research, business development and industry partnerships.

Total enrolment onto sub-studies to September 2020: 120 patients.

5 sub-studies recruiting8 sub-studies in start up3 substudies in development

New treatment sub-studies concepts are developed by harnessing ideas from an expanded Clinical Trial Working Group (CTWG), with representation from all states and territory members, sub-program leadership and a growing group of motivated research fellows. Regular meetings are held to review new concepts, trial progress and brain storm proposals for treatment options.

The establishment of this infrastructure has resulted in an increase in the number of proposals and an increase in the number of concepts attracting industry support. The number of clinicians involved within the precision oncology space has grown, allowing us to harness and add the expertise of these emerging leaders to genomics research and utility,



Current Sub-study pipeline and status:

Sub	studies in recruitment or follow-up:	Status	Recruitment/target
1.	Durvalumab and Tremelimumab (pan cancer)	in treatment and follow up	49/49
2.	Olaparib and Durvalumab (pan cancer)	in treatment and follow up	49/49
3.	Vismodegib (pan cancer)	recruiting	9/16
4.	Eribulin(pan cancer)	recruiting	8/16
5.	Trastuzumab emtansine (Kadcyla) (pan cancer)	recruiting	5/32
	Trastuzumab emtansine (Kadcyla) (ASPiRATION)	from 2021	0/32
6.	Larotrectinib (pan cancer)	recruiting	0/32
7.	Tremelimumab (pan cancer)	recruting	0/48
Sub	studies in start up or development		Target recuitment number
1.	Tucatinib and trastuzumab (pan cancer)	start up	32
2.	Palbociclib plus avelumab (pan cancer)	start up	32
3.	Tildrakizumab (pan cancer)	start up	32
4.	Vemurafinib and cobimetinib (combined pan cancer and ASPiRATION)	start up	64
5.	Entrectinib (combined pan cancer and ASPiRATION)	start up	16
6.	Alectinib (pan cancer and ASPiRATION)	start up	16
7.	Acalabrutinib plus durvalumab (haematology)	start up	32
8.	Pamiparib (blood cancer)	start up	16
9.	Tepotinib (pan cancer and ASPiRATION)	in development	32
10.	Chemotherapy plus Durvalumab (non-lung)	in development	16
11.	AMG510 (pan cancer)	in development	32
		Total target recrutiment numbers to date	591

MoST long-term follow-up unit (LTFU)



The long-term follow-up unit (LTFU) was established in mid 2019 to look at the feasibility and benefit of a molecular screening platform for patients with advanced cancer and unmet need.

> 84% of data collected for 1324 patients with at least 12 months elapsed since their MTB report was issued

The unit is collecting information about patients at a number of time points throughout their cancer journey. Information includes, overall survival (death of any cause), progression free survival, performance status, treatment history and whether the clinician believed molecular screening provided benefit and barriers to receiving recommended therapies.

In September 2020 the follow up unit expanded to manage the increasing demand on data collection as the molecular screening cohort for pan-cancer, lung cancer and others in the pipeline, grows. Over last 12 months the LTFU has developed remote (secure) data collection instruments to supplement the more traditional methods of data collection e.g. phone, fax and email. This has meant that COVID-19 has had little effect on our progress, but has allowed efficiencies in the follow up procedures to be identified and implemented.

We have implemented procedures that place patient follow-up front of mind, including requesting an update on the patient's performance status from the referring clinician at the time the molecular tumour board (MTB) report is issued. This allows us to capture information about patients who may be too unwell to benefit from molecular screening.

Data collection to date:

- follow-up has been prioritised for 1324 patients with at least 12 months elapsed since their MTB report was issued. The follow-up completion rate is currently 84%. Our aim is an 80% completion rate with a 'lost to follow up' rate of 20% being acceptable for this cohort where patients have been referred from approximately 150 institutes nationally.
- Overall survival (date of death) has been collected for 860 (64.3%) of these patients.



All patients with MTBs issued until 15th September 2019 (12 months follow up)	Unmatched therapy	Matched therapy (MoST trial)	Matched therapy (other trial/access)	Any matched therapy as a result of MoST screening
n	826	174	82	256
Median Survival (weeks)	53	64	94	71
Log-rank (Mantel-Cox) P value		0.0886	0.0045	0.0042
Gehan-Breslow-Wilcoxon P value		0.0045	0.0016	p<0.0001
HR (Log-Rank)		0.84	0.62	0.77
95% CI of ratio		0.69-1.02	0.47-0.82	0.64-0.91

Kaplan-Meier survival analysis of patients who received a matched therapy as a direct result of MoST screening compared to those that did not received a matched therapy

Interim results indicate that molecular screening provides benefit for patients

Of the 1082 patients with 12 months follow up to date:

- A therapeutic recommendation was provided for 708 patients (65.4%) well enough to receive therapy.
- 174 patients (16.1%) have enrolled onto a MoST signal seeking clinical sub study as a direct result of MoST molecular screening with the median survival of this cohort 64 weeks (see Kaplan-Meier graphs above).
- Another 82 patients (7.6%) received a matched

therapy due to a clinical decision based on the MoST molecular screening with the median survival of this cohort 94 weeks (see Kaplan-Meier graphs above).

- Overall, 256 patients (23.7%) or 36% of all patients who had a MTB report with at least one therapeutic recommendation received a matched therapy as a direct result of MoST molecular screening, with a median survival of 71 weeks compared to 53 weeks for those patients who did not receive a matched therapy (Logrank P value 0.0042, HR 0.77 (95% CI 0.64-0.91) (see Kaplan-Meier graphs above).
- The most commonly followed treatment recommendations as a result of MoST screening and outside of a MoST clinical trial were immunotherapy (28.0%) followed by mTOR inhibitors and ERBB2 inhibitors (11.0%), PARP inhibitors (9.8%) and CDK4/6 inhibitors (8.5%).



Longterm follow-up can identify areas of greatest clinical need

The most common barriers to receiving a recommended therapy were:

- 1. the therapy could not be accessed (via a clinical trial or other means) (56.7% of all responses) and
- 2. a lack of confidence in the recommendation (11.1% of all responses).

The most common difficult to access drug classes: FGFR inhibitors (12.1%), PI3K inhibitors (11.0%), EGFR inhibitors (8.8%), MEK inhibitors (7.7%) and CDK4/6 inhibitors (6.6%)*.

One clinician commented that they 'tried to source erdafitinib (for a FGFR fusion molecular alteration) but was quoted \$147,000 per month, obviously not possible for the patient' another commented that 'obtaining drugs for a non-indicated cancer is often very expensive and often not an option'.

*the MoST clinical trials working group are addressing these urgent areas of clinical need through the development of sub-studies targeting these drug classes.

On a personal note

Case study 1.

A 75-year-old women who was diagnosed with an epithelioid hemangioendothelioma at age 69 in the left pleura of the lung with distant metastasis. She was one of the very early consents to MoST in October 2016 with an MTB report issued in March 2017 which found no actionable alterations except for single copy CDKN2A loss which was confirmed by FISH. This qualified her for enrolment into MoST2 Durvalumab and Tremelimumab on which she spent 889 days on trial with stable disease throughout the course of this trial. The patient came off the MoST trial in April 2020 and has just been enrolled on a second immunotherapy trial aimed at enhancing T-cell response. On patient interview, the patient mentioned that she is having some pain related issues but otherwise is well. The patient stated that she was 'thankful to MoST' and felt that the 'dual *immunotherapy she received on the MoST trial was* great and that she knows it kept her cancer at bay'

Case Study 2.

Α 53-year-old man diagnosed with lung adenocarcinoma in November 2014 with distant metastasis heavily pre-treated with surgery, radiation, chemotherapy and 13 cycles of immunotherapy (nivolumab). We performed molecular screening on this patient in July 2018 that revealed a gain of function mutation in MET for which we recommended tyrosine kinase inhibitors. The tumour also had an MDM2 amplification, CHEK1 duplication and an MLH1 mutation. The patient initially received cabozantinib matched therapy on which his brain metastases progressed. He was then placed on a second matched therapy, MET inhibitor capmatinib and had a complete response with his scans now clear. The patient stated that 'MoST screening had provided him benefit by recommending the class of drugs that would be effective against his cancer'.



Our patients are grateful for the presence of the program whether they get a treatment recommendation or not

Case Study 3.

A 30-year-old man consented to MoST in December 2016 originally with a rare EWSR1 positive angiomatoid fibrous histiocytoma of the thorax (near spine) with distant bone metastases and heavily pretreated with surgery, radiation and chemotherapy. We performed molecular screening on this tumour in April 2017 with no actionable alterations found qualifying this patient for the MoST durvalumab and tremelimumab sub study. The patient completed the full regimen of 13 cycles with stable disease as best outcome. Since coming off sub study, the patient has had further surgery to resect metastatic deposits and had an amputation of the right proximal femur but has not received any further systemic treatments. On interview the patient stated that 'He was doing great and that he was thankful to MoST for the outcomes he has had. He further added that the 'MoST program was wonderful about how they approached everything to do with the screening, cancer and therapeutics.' He further stated 'that nothing was available to him before he was screened on MoST for his rare cancer and went onto the clinical sub study'

Case study 4.

A 39-year-old woman diagnosed with a locally advanced glioblastoma at age 33. The patient had a debulking surgery and radiotherapy but as the tumour was large and in the eloquent cortex, it could not be fully removed. The MTB report issued in early 2018 reporting that the tumour had an IDH1 mutation which we recommended temozolomide, as well as an NTRK fusion with an NTRK inhibitor recommendation, PIK3CA mutation with a PI3K inhibitor recommendation and finally a TP53 mutation. The patient was already receiving temozolomide chemotherapy at the time of receiving the report and after receiving our report continued on maintenance temozolomide which is still current as of June 2020. The patient has a complete response to temozolomide and is considered an exceptional responder by the clinician. On interview the patient commented that 'she was doing very well, she is very happy with her treatment and even though that her treatment was not changed as a result of screening, she was thrilled that her participation in the trial was extremely important for our research'.

Translational Oncology Laboratory (TOL)

The Translational Oncology Laboratory (TOL) was set up in 2018 to facilitate the in-depth molecular and biological analysis of tissue samples from patients enrolled onto MoST. The laboratory undertakes a wide range of analyses that focus on identifying retrospective and prognostic biomarkers of disease and response to treatment, and correlates these with clinical outcomes.

Our current focus is on two of the larger MoST substudies. The first is investigating the response of rare and neglected cancers to dual immune checkpoint blockade (Durvalumab targeting PD-L1 and Tremelilumab targeting CTLA-4, Durva/ Treme). The study completed the recruitment of 112 patients, last patient - Dec 2019. Patient samples continue to be examined for tumour and immune cell associated PD-L1 expression, tumour mutation burden, transcriptional immune profiling in tumour using Nanostring TM, lymphocyte to neutrophil ratio in blood, cytokines -IL6, IL10 and IFNG in plasma pre and post-treatment, abundance of immune cells subtypes and markers of activation and exhaustion in peripheral blood mononuclear cells (PBMCs). We have started to get some of the results from T-cell receptor repertoire and clonality in baseline tumour and bloods pre and post treatment. The graph shows a patient sample showing T-cell receptor clonal diversity and abundance in the tumour prior to treatment and in the blood at baseline and following treatment. You can see the presence of clones in tumour and in blood and expansion of clones following treatment, this is an example of a patient who had a partial response. Single cell transcriptomic analysis has been conducted on available PBMCs pre and post treatment and is currently being analysed.

The second sub-study investigates the PARP inhibitor Olaparib in combination with immune checkpoint blockade drug Durvalumab in a total of 48 patients. Similar studies as described above are being conducted in this cohort.

For the Larotrectinib sub-study we will be assessing pan-TRK expression in suspected NTK fusion tumours.



Graph of a patient sample showing T-cell receptor clonal diversity and abundance in tumour at baseline and bloods at baseline and at 4 weeks following treatment with dual immune checkpoint blockade.

Genetic Cancer Risk in the Young (RisC) study



In Australia there are more than 250,000 survivors of childhood or young adult cancer. Early onset cancers represent a significant burden of cost, morbidity and mortality to the community. Evidence suggests that cancer in the young is largely driven by heritable causes and there is a higher risk of developing a second cancer as well as implications for family members.

Suspected germline mutations and genetic testing are relevant to cancer treatment and prevention.

The RisC study is a clinical genomics program for early-onset cancers. RisC, and its companion the Surveillance in Multi-Organ Cancer-Prone Syndromes (SMOC+) study, have already identified cancers at an earlier, curable stage.

The RisC study uses heritable genetic infomation to assess cancer predisposition and investigate clinical risk management, including whole-body MRI, in this high-risk population.

Individuals are recruited into the study based on the following characteristics:

- Patients diagnosed with any solid cancer aged 16-40 years
- Biological parents of patients

Towards the end of September 2020, 1321 cancer probands* across Australia (see graphs on the next page) (55% female) had been enrolled onto the RisC study. More than 20% of probands have had multiple primary cancers and diverse cancer types have been observed. * a proband is a person serving as the starting point for the genetic study of a family





The different cancer types identified in RisC patients

Surveillance in Multi-Organ Cancers (SMOC+) study

The SMOC+ study aims to estimate the prevalence and incidence of investigable lesions using protocols (including whole-body magnetic resonance imaging (WBMRI) customised by genotype for individuals at increased risk of cancer. Participation in the surveillance phase of the SMOC+ study involves annual whole-body MRI (WBMRI), physical examination and clinical review, blood test and completion of questionnaires.

The SMOC+ study has been established in New South Wales, Victoria and South Australia. As at mid September 2020, 91 subjects have been consented to participate in SMOC+ - 9 patients were consented in the period 1 January to 30 June 2020.

Twenty four (24) localised asymptomatic cancers have been identified in 22 of the 91 individuals who have completed at least one WBMRI (25%). In collaboration with the Sydney Children's Hospital a SMOC Junior protocol is being developed to investigate surveillance in children at high risk of developing cancer.

SMOC+ has addressed an unmet clinical need for surveillance in highly cancer-prone populations where there are no Australian guidelines that consider the multi-organ nature of cancer risk in many hereditary syndromes.

Omico has prepared the first stage of an application to the Medical Services Advisory Committee for consideration of annual whole body MRI for TP53 mutation carriers. This has been done in collaboration with the Centre for Economics Impacts of Genomic Medicine (GenIMPACT) at Macquarie University led by Professor Deborah Schofield and included economic modelling utilising Medicare/ Pharmaceutical Benefits Scheme data from the existing SMOC+ cohort. In future this modelling will be extrapolated to the high risk population identified in the RisC study.



Advocacy and Support

Rare Cancers Australia (RCA)

Patient Support Program – The RCA Patient Care Team has added an additional Patient Care Coordinator (now 3.5 FTE) and is currently providing support via direct contact (verbal or written) to 442 active patients with either rare or less common cancers. Additionally, they have established peerto-peer support groups for the following categories:

- GIST Support Group
- Rare Cancer Carers Group
- Rare Cancers Tumour Agnostic
- Medullary Thyroid Carcinoma Group
- Thymoma Group
- Sarcoma Group

These groups have been extremely well received with over 50 patients and carers already signing up for the sessions

In the period 1 July 2019 to 30 June 2020

RCA has delivered digital, verbal or written information to over 10,000 individuals. This includes 5,000 views of the videos featuring Prof Thomas and Dr Ballinger discussing genomic medicine and the MoST program. There were also over 1,500 listens to the Radio Rare podcasts. More episodes are in production.

Whilst the AGCMC and the MoST features across all mediums, of those patients with direct verbal or written contact, 135 patients have been provided information relating to the AGCMC Program (MoST).

Centre Visits - RCA staff have visited 2 sites (Sydney and Melbourne) and are scheduling visits to the other sites over the coming months. These visits have been deferred due to COVID-19 and we are exploring video information.

Web presence – RCA launched a new patient-centric website on 10 February 2020. To further enhance the site RCA has also produced a series of easily understood videos which explain complex subjects such as clinical trials, personalised medicine and the MoST study. Additional information in written and video form has been supplied to patients on the impact of COVID-19 on cancer patients and trials. Videos have been viewed over 5000 times.

Professionalise data collection within the RCA program – RCA has installed and enhanced a Patient Database that allows secure and accurate storage of non-clinical data and provides accurate information on patient metrics over the course of the AGCMC program and beyond.

Social media engagement – RCA has developed a patient support strategy specific to social media platforms. In summary:

- LinkedIn post impressions averaging 6,000 per month
- 83,000 Engagements on Facebook for the year ending 30 June 2020
- Audience engagement measured at 31% twice that of comparable organisations

Patient Advisory Board – RCA has established a 12-person Patient Advisory Board to provide constant input on initiatives including patient support focus, new resources, website, social media and patient focussed/centric events.

Transport & Accommodation – RCA has put in place processes and procedures to manage logistics for patients in need of assistance for travel and accommodation. RCA has commenced providing assistance and has reserved significant funds for this process.

Advocacy & awareness – RCA staff have manned exhibitor booths at the Cancer Nurses Congress, Clinical Oncology Society of Australia ASM and the Medical Oncology Group of Australia ASM in 2019. These events have provided excellent opportunities to raise awareness of the AGCMC within HCP networks.

Additionally, RCA is conducting an ongoing media campaign on the subject of genomic science and is planning a major event in November in Parliament House, Canberra. This event will be supported by a



major report detailing the opportunities presented by genomic medicine.

Government & Public Policy – RCA is working with AGCMC to form policies that can be presented to Federal and State Government to continually emphasise the need for ongoing support and funding of the Program. Initiatives include events in Federal Parliament, media campaigns and production of relevant policy papers. Specific policy initiatives have been agreed with AGCMC and will roll out over the coming months:

- Campaigning for the reform of MSAC processes as they apply to various genetic testing. RCA has commissioned a report aimed at developing funding mechanisms for genomic screening of advanced cancer patients. It is expected this report will be completed by 31 August 2020.
- RCA is working with AGCMC and others to produce a report that outlines a vision for cancer care over the next decade to 2030. The report will make the case for government to prepare a National Cancer Plan based on the trajectory of cancer science and therapies over the coming decade. This report will be launched in Canberra on 9 November 2020

Referral Packs - RCA has developed information packs for patients, clinicians and treatment centres regarding the challenges faced by patients with rare cancers. RCA will use its resources to assist in distribution of information throughout the community.

Communications-RCA has retained communications consultants to develop a comprehensive communications strategy built around the emerging science championed and developed by the AGCMC

RCA are delighted to be part of the AGCMC, and are pleased with their achievements as they progress through the project. They look forward to continuing to provide substantial support and contribute over the coming years. A place to learn, someone to listen, help with navigating the journey or advice



Rare Cancer Portal

The Australian Rare Cancer (ARC) Portal is an online service assisting cancer specialists caring for patients with a rare cancer. It streamlines rare cancer care by providing a singular access point for clinical guidance, molecular interpretation, and nationwide expertise. The ARC Portal is helping ensure patients with rare cancers have appropriate access at the right time during their cancer journey to AGCMC genomic programs and will facilitate rare cancer research in partnership with the WEHI Stafford Fox Rare Cancer (SFRC) Program.

The ARC Portal is embedded within BioGrid Australia. BioGrid Australia is a not for profit company owned by the research sector. Data governance and patient privacy are core capabilities of BioGrid, and its federated data sharing platform securely links patient level clinical, bio-specimen, genetic variance, imaging and administrative datasets from multiple sources for the purpose of ethically approved medical research.

Key achievements thus far include:

Development of the ARC Portal Website and Online Referral Service - now available at: www.arcportal. org.au<http://www.arcportal.org.au/>. This website has been designed to help clinicians and patients learn about rare cancers and rare cancer research; and access curated resources - as well as the ARC Portal's online referral service. Clinicians (or their approved delegates) can register and quickly enrol patients and create new patient referrals.

Referrals are processed and tracked through a workflow involving portal clinicians, referral specialists and potential MDM review. During this process clinical data and specialist feedback is curated to an underlying database to help build

> streamlining rare cancer care by providing a single point of access for clinical guidance

a knowledge base which is used to streamline future referrals. The database is aligned to share de-identified data with that of the SFRC program, helping to underpin rare cancer research.

Ethics approval has been completed allowing for remote patient consent. Currently this is done via downloaded consent forms and is supported by a genetic counsellor. Future developments will include a completely online consent process. A pending ethics amendment will expand access from rural/ regional patients to include metropolitan patients.

Initial launch - the ARC Portal has opened to referrers in Tasmania and a select few in regional Victoria/ NSW for early testing. This has been opportune, providing rare cancer support for clinicians/patients impacted by travel restrictions during early 2020. More than 270 patients have been processed through the Portal and have provided consent for involvement in research.

https://www.arcportal.org.au/

Research outputs

Publications

- Malkin D, Bond G, Thomas DM, Ballinger ML, World Health Organisation Classification of Tumours – Soft Tissue and Bone 5th edition, Vol 3. 2019. Li Fraumeni Syndrome.
- Ballinger ML, Pinese M and Thomas DM (2019). Translating genomic risk into an early detection strategy for sarcoma. Genes Chromosomes Cancer 58: 130-136.
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- McCabe MJ, Pinese M, Chan CL, Sheriff N, Thompson TJ, Grady J, Wong M, Gauthier MA, Puttick C, Gayevskiy V, Hajdu E, Wong SQ, Barrett W, Earls P, Lukeis R, Cheng YY, Lin RCY, Thomas DM, Watkins DN, Dinger ME, McCormack AI and Cowley MJ (2019). Genomic stratification and liquid biopsy in a rare adrenocortical carcinoma (ACC) case, with dual lung metastases. Cold Spring Harb Mol Case Stud 5: pii: a003764.

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- Yanes T, Willis AM, Meiser B, Tucker KM, Best M. (2019). Psychological and behavioural outcomes of genomic testing in cancer: a systematic review. European Journal of Human Genetics; 27: 28-35.

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Presentations - International

2020

- May 2020 D Goldstein ASCO20 Virtual Scientific Program - Return of results after somatic tumour mutation profiling in advanced cancer: Psychological impacts (poster)
- June 2020 C Napier European Society of Human Genetics (ESHG) 2020.2 – Live in your living room: How much do cancer patients value whole genome sequencing? A cross-sectional survey using the willingness-to-pay technique (poster)
- September 2020 D Thomas Invited speaker -Roche UTEC Precision Medicine Symposium, Peru: Establishing a national program in precision oncology: the Australian experience?
- October 2020 D Thomas Invited speaker 5th International LFS Association Symposium: A landscape map of biological pathways driving risk for sarcomas: the International Sarcoma Kindred Study
- October 2020 D Thomas Invited speaker Japanese Cancer Association 2020 Annual Meeting: MTOR signaling orchestrates stressinduced mutagenesis facilitating adaptive evolution in human cancers

- March 2019, D Thomas Invited speaker e-ASIA "Rare Cancer" workshop, Singapore: Precision oncology
- March 2019, D Thomas Keynote speaker Japan Agency for Medical Research and Development (AMED) Asia-Pacific Scientific Workshop, Singapore: Towards an Australian Genomic Cancer Medicine Program
- March 2019, D Thomas Invited speaker Japan Agency for Medical Research and Development (AMED) Asia-Pacific Scientific Workshop, Singapore: Rare cancers: Translation of genetic sarcoma risk into an effective early detection program

- March 2019 D Thomas Invited speaker -International Medical Education Leaders Forum (IMELF) Australasia, March, Auckland, New Zealand): The Australian Genomic Cancer Medicine Program
- April 2019 D Thomas Invited speaker Maine Cancer Genome Initiative Annual Meeting, Maine, USA : Towards an Australian Genomic Cancer Medicine Program
- May 2019 M Ballinger Invited speaker Scandinavian Sarcoma Group 39th Plenary Meeting, Li Fraumeni Workshop, Bergen, Norway, Surveillance in Li Fraumeni syndrome
- May 2019 M Ballinger Invited speaker -Scandinavian Sarcoma Group 39th Plenary Meeting, Li Fraumeni Workshop, Bergen, Norway, Psychosocial impact of surveillance in Li Fraumeni syndrome
- May 2019 D Thomas Invited plenary speaker -Scandinavian Sarcoma Group 40-year Jubilee meeting, Bergen, Norway: Genetics and Oncologic Therapy
- June 2019 M Best 17th International Conference on Communication, Medicine and Ethics, Adelaide, Australia
- June 2019 M Best European Human Genetics Conference, Gothenberg, Sweden, Advanced cancer patient perspectives on consenting to molecular tumour profiling
- June 2019 S Thavaneswaran ASCO Annual Meeting, Chicago, USA, Medical Oncologists' experiences with returning molecular tumour profiling to patients. (poster)
- June 2019 S Thavaneswaran ASCO Annual Meeting, Chicago, USA, The Molecular Screening and Therapeutics Program – actionable mutation frequencies in a population with rare and less common cancers. (poster)
- September 2019 N Bartley International Psycho-Oncology Society World Congress, Banff, Canada, Cancer patients' views and understanding of genome sequencing: a qualitative study (oral)

- September 2019 N Bartley International Psycho-Oncology Society World Congress, Banff, Canada, A systematic review of patient uncertainty when undertaking cancer genomic testing (poster)
- November 2019 M Best Joint meeting of IMPAHC, HEBON and VKGN on Challenges in Cancer Genetics 2019, Leiden, Netherlands, Cancer patient knowledge and attitudes towards germline genome sequencing (oral)
- November 2019 N Bartley Joint meeting of IMPAHC, HEBON and VKGN on Challenges in Cancer Genetics 2019, Leiden, Netherlands, Fear of cancer recurrence and uncertainty in patients undergoing whole genome sequencing (oral)
- November 2019 M Best Joint meeting of IMPAHC, HEBON and VKGN on Challenges in Cancer Genetics 2019, Leiden, Netherlands, Family communication about genomic testing: A qualitative study (poster)
- November 2019 N Bartley Joint meeting of IMPAHC, HEBON and VKGN on Challenges in Cancer Genetics 2019, Leiden, Netherlands, Cancer patient uncertainty when pursuing whole genome sequencing: a qualitative study (poster)
- November 2019 M Kansara Invited speaker -Connective Tissue Oncology Society Meeting (CTOS), Tokyo, Japan: Survey of Actionable Genomic Alterations in a Cohort of Soft Tissue and Bone Sarcomas
- 20. November 2019 D Thomas Invited speaker -Roche Global Expert Meeting, Munich, Germany: Precision oncology: where have we come from, where are we today, and where are we going?
- 21. December 2019 D Thomas Invited speaker -Roche FMI Media Event, Zurich, Switzerland: The Australian Genomic Cancer Medicine Centre

Presentations - National

2020

- February 2020 D Thomas Invited speaker

 Lorne Genome Conference, Victoria: A quantitative pathway-based whole genome rare variant analysis of 1,600 individuals affected by sarcoma
- February 2020 D Thomas Invited speaker Lung Cancer Foundation Community Forum, Victoria: Personalized medicine – Advancements, access & understanding in genomics
- February 2020 S Thavaneswaran Invited speaker

 Centre for Oncology Education and Research Translation (CONCERT) T1/T2 Workshop: Presented the MoST study – Precision medicine approach to clinical trials
- February 2020 M Kansara Invited speaker Clare Valley Bone Conference, South Australia: Bench to beside; New Therapeutic Opportunities in Osteosarcoma.
- February 2020 M Kansara Invited speaker
 Children's Oncology Symposium, Hudson Institute, Victoria: Osteosarcoma and IL23
- March 2020 M Ballinger Invited speaker The Royal College of Pathologists of Australia Pathology Update (cancelled): Heritable cancer risk in the genomic era
- June 2020 M Ballinger Invited speaker National Oncology Alliance Vision 2030 Workshop, online forum – Healthy lives will help to rebuild the economy and unburden the health system
- August 2020 M Ballinger Invited speaker Children's Cancer Research Unit 2020 seminar series, Kid's Research Westmead: Surveillance study in multi-organ cancer prone syndromes

- 1. February 2019 D Thomas Invited speaker Lorne Genome Conference, Victoria: MTOR signaling orchestrates stress-induced mutagenesis facilitating adaptive evolution in human cancers
- February 2019 D Thomas Invited speaker St Vincent's Health Australia Research Forum, Victoria: Precision oncology: the Australian Genomic Cancer Medicine Program
- 3. March 2019 D Thomas Invited speaker -International Academy of Pathology (IAP) meeting, Sydney : Biomarker-driven trials
- 4. March 2019 D Thomas Invited speaker Drug Development Conference 2019, March, Sydney : Precision oncology trials
- April 2019 M Ballinger Invited speaker Sydney Children's Hospital Paediatric Oncology Journal Club, Sydney : Surveillance in Li Fraumeni Syndrome
- June 2019 N Bartley Sydney Catalyst Postgraduate and Early Career Researcher Symposium, Sydney : Uncertainty experienced by adults undertaking cancer genome sequencing: Systematic review
- 7. July 2019 M Ballinger Invited speaker ANZSA Scientific Advisory Committee Meeting, Sydney
- 8. August 2019 M Ballinger Invited speaker -Familial aspects of Cancer: Research and Practice (KConFab), Kingscliff QLD, Family communication about genomic testing: Surveillance in Li Fraumeni Syndrome: the Australian experience
- August 2019 M Ballinger Invited speaker NSW Family Cancer Clinic Meeting: Surveillance in Li Fraumeni Syndrome
- August 2019 S Thavaneswaran Invited speaker

 Medical Oncology Group Australia Annual Scientific Meeting - Leading the Way in Medical Oncology Education, Research and Clinical Practice: Molecular Profiling and Precision Oncology.



- August 2019 M Best Familial aspects of Cancer: Research and Practice (KConFab), Kingscliff QLD, Family communication about genomic testing: A qualitative study (oral & poster)
- August 2019 M Best Familial aspects of Cancer: Research and Practice (KConFab), Kingscliff QLD, Cancer patient knowledge and attitudes towards germline genome sequencing (oral)
- September 2019 D Thomas Invited speaker

 Australian Genomics National Conference 'Genomics in Australian healthcare: foundations to future', Melbourne: The Cancer Risk in the Young Study
- September 2019 D Thomas Invited speaker -Human Genetics Society of Australasia Annual Branch Symposium, Adelaide: The International Sarcoma Kindred Study
- September 2019 P Butow Sydney Catalyst International Translational Cancer Research Symposium, Sydney, The Psychosocial Issues in Genomic Oncology (PiGeOn) Project (oral)
- 16. September 2019 N Bartley Sydney Catalyst International Translational Cancer Research Symposium, Sydney, Cancer patients' views and understanding of genome sequencing: a qualitative study (oral & poster)
- September 2019 C Napier Sydney Catalyst International Translational Cancer Research Symposium, Sydney, Patient perspectives on molecular tumor profiling: "Why wouldn't you?" (poster)
- September 2019 A Smit Sydney Catalyst International Translational Cancer Research Symposium, Sydney, Who should access Germline Genome Sequencing? A mixed methods study of patient views (poster)
- September 2019 A Smit Sydney Catalyst International Translational Cancer Research Symposium, Sydney, Advanced cancer patients' preferences or return of molecular profiling results (poster)

- 20. September 2019 N Bartley Sydney Catalyst International Translational Cancer Research Symposium, Sydney, Why do patients pursue cancer genomic testing? A systematic review of motivation. (poster)
- 21. September 2019 N Bartley Sydney Catalyst International Translational Cancer Research Symposium, Sydney, Why do patients pursue cancer genomic testing? A systematic review of motivation. (poster)
- 22. October 2019 M Ballinger Invited speaker St Vincent's Hospital, Medical Oncology Education Program, Sydney: Surveillance in Li Fraumeni Syndrome
- 23. October 2019 M Ballinger Invited speaker ANZSA ASM, Canberra: Surveillance in Multi-Organ cancer prone syndromes
- 24. October 2019 M Ballinger Invited speaker PeterMac Familial Cancer Centre & Genomic Medicine Seminar, Melbourne: Surveillance in Li Fraumeni Syndrome
- 25. October 2019 M Kansara Invited speaker -ANZSA ASM, Canberra: Novel drug targets in osteosarcoma bench to bedside
- 26. October 2019 D Thomas Invited speaker -Australian Medical Research Institute (SAHMRI) 2019 Annual Scientific Meeting, Adelaide: The International Sarcoma Kindred Study: a whole genome analysis
- October 2019 D Thomas Invited speaker MSD Drug Discovery & Development in Oncology Symposium, Melbourne: The MoST study: a national precision oncology basket trial
- 28. November 2019 M Ballinger Invited speaker CanTeen Youth Cancer Services Workshop, Adelaide: AYA-MoST: a Molecular Screening & Therapeutics trial for adolescents and young adults with advanced cancer
- November 2019 M Ballinger Invited speaker 2nd Australian Precision Oncology Symposium, Adelaide: Closing the loop – managing genetic cancer risk.



- November 2019 D Thomas Invited speaker 2nd Australian Functional Genomics Conference, Sydney: Interpretation of genetic variation in precision oncology
- November 2019 D Thomas Invited speaker 2nd Australian Precision Oncology Symposium, Adelaide: Early onset cancer - public health perspective
- 32. November 2019 S Thavaneswaran Invited speaker 2nd Australian Precision Oncology Symposium, Adelaide: the Molecular Screening and Therapeutics Program
- 33. November 2019 C Napier 2nd Australian Precision Oncology Symposium, Adelaide: Patient knowledge of and attitudes towards tumour molecular profiling (poster)
- 34. November 2019 C Napier 2nd Australian Precision Oncology Symposium, Adelaide: Patient perspectives on molecular tumor profiling: "Why wouldn't you?" (poster)
- November 2019 P Butow Invited speaker 2nd Australian Precision Oncology Symposium, Adelaide: The Psychosocial Issues in Genomic Oncology (PiGeOn) Project.
- November 2019 P Butow PoCoG ASM, Adelaide: Advanced cancer patient preferences for return of molecular profiling results (oral)
- November 2019 P Butow PoCoG ASM, Adelaide: Family communication about genomic testing: a qualitative study (oral)
- November 2019 G Davies PoCoG ASM, Adelaide: Why do patients pursue cancer genomic testing? A systematic review of motivation (poster)
- 39. 3November 2019 G Davies PoCoG ASM, Adelaide: Who should access Germline Genome Sequencing? A mixed methods study of patient views (poster)
- 40. November 2019 P Butow PoCoG ASM, Adelaide: Cancer patients' views and understanding of genome sequencing: a qualitative study (poster)
- 41. November 2019 G Davies PoCoG ASM, Adelaide: Patient knowledge of and attitudes towards tumour molecular profiling (poster)

- 42. November 2019 G Davies PoCoG ASM, Adelaide: Cancer patient knowledge, attitudes, and fear of cancer recurrence when pursuing germline genome sequencing (poster)
- 43. November 2019 P Butow COSA ASM, Adelaide: Patient perspectives on molecular tumour profiling: "Why wouldn't you?" (poster)
- 44. November 2019 P Butow COSA ASM, Adelaide: Who should access Germline Genome Sequencing? A mixed methods study of patient views. (oral)
- 45. November 2019 M Best COSA ASM, Adelaide: Advanced cancer patient preferences for return of molecular profiling results. (oral)
- 46. November 2019 G Davies COSA ASM, Adelaide: Patient knowledge of and attitudes towards tumour molecular profiling (poster)
- 47. November 2019 M Kansara Invited speaker 2nd Australian Precision Oncology Symposium, Adelaide: Correlative Science for an Immunotherapy Substudy



1

ABN 67 627 640 733

Financial Report

For the year ended 30 June 2020



Contents

Corporate Information Statement	3
Statement of profit or loss and other comprehensive income	4
Statement of financial position	5
Statement of changes in funds	6
Statement of cash flows	7
Notes to the financial statements	8
Declaration by the Principal Officer	16
Responsible Entities' Declaration	17
Auditor's Independence Declaration	18
Independent Audit Report	19



Corporate Information Statement

Australian Genomic Cancer Medicine Centre Limited is a company limited by guarantee and registered with the Australian Charities and Not-for-profit Commission.

ABN 67 627 640 733

Responsible Entities

The following Directors (Responsible Entities) were in office at the date of this report:

Mr Paul Jeans (Chair) Mr Richard Vines (Deputy Chair) Professor Michael Brown Professor Christopher Goodnow Mr Bruce Goodwin Professor Ricky Johnstone Ms Tze Masters Professor Kathryn North Professor John Simes Professor David Thomas Emeritus Professor Mark Wainwright AM

Company Secretary

Associate Professor Paul Martin

Chief Executive Officer

Professor David Thomas

Address

L7 The Kinghorn Cancer Centre 370 Victoria Street Darlinghurst NSW 2010 Australia

Auditor

Grant Thornton



Statement of profit or loss and other comprehensive income

For the year ended 30 June 2020

	Note		
	Note	2020 \$	2019 \$
Revenue from operations Interest income	2	10,705,326 158,440	10,000,000 67,301
Total revenue and other income		10,863,766	10,067,301
Service provider and project expenses	3	(8,304,750)	(750,000)
Consulting and support services expenses	4	(509,502)	(289,967)
Employee costs		(198,920)	(49,275)
Other administrative costs		(177,982)	(59,600)
Total costs		(9,191,154)	(1,148,842)
Surplus for the Year	_	1,672,612	8,918,459
Other comprehensive income			
Total comprehensive income for the year		1,672,612	8,918,459

The statement of profit or loss and other comprehensive income is to be read in conjunction with the notes to the financial statements.



Statement of financial position

As at 30 June 2020

	Note	2020 \$	2019 \$
Assets			·
Current assets			
Cash and cash equivalents	5	12.967.029	8.910.102
Accrued income	-	9.748	-
Prepayments	6	-	577
Receivables	7	244,976	69,582
Total current assets	-	13,221,753	8,980,261
Total assets	_	13,221,753	8,980,261
Liabilities			
Current liabilities			
Contract liability		2,500,000	-
Trade payables and accruals	8	130,682	61,802
Total current liabilities	-	2,630,682	61,802
Total liabilities	-	2 620 692	64 900
	-	2,630,682	61,802
Net assets	-	10,591,071	8,918,459
Funds			
Accumulated surplus	0	10 501 071	0 010 150
Total funde	ษ _	10,591,071	0,910,409
i otai iulius		10,591,071	0,910,459

5

The statement of financial position is to be read in conjunction with the notes to the financial statements.



Statement of changes in funds

For the year ended 30 June 2020

	Accumulated Funds \$	Total Funds \$
Balance at 20 July 2018 (date of incorporation)	-	-
Surplus for the period Other comprehensive income for the period	8,918,459 -	8,918,459 -
Total comprehensive income for the period	8,918,459	8.918,459
Balance at 1 July 2019	8,918,459	8,918,459
Surplus for the year Other comprehensive income for the year	1,672,612 -	1,672,612 -
Total comprehensive income for the year	1,672,612	1,672,612
Balance at 30 June 2020	10,591,071	10,591,071

The statement of changes in funds is to be read in conjunction with the notes to the financial statements.



Statement of cash flows

For the year ended 30 June 2020

Note	2020 \$	2019 \$
	13,750,000	11,000,000
	775,860	-
	(10,617,625)	(2,157,199)
	148,692	67,301
10	4,056,927	8,910,102
	4,056,927	8,910,102
	8,910,102	-
5	12,967,029	8,910,102
	Note 10 5	Note2020 \$13,750,000 775,860 $(10,617,625)$ $148,692$ 10 $4,056,927$ $4,056,927$ $8,910,102$ 5 $12,967,029$

7

The statement of cash flows is to be read in conjunction with the notes to the financial statements.

Notes to the financial statements

Australian Genomic Cancer Medicine Centre Limited ("AGCMC") is a company limited by guarantee that was incorporated on 20 July 2018. AGCMC is domiciled in Australia. The Company is a not-for-profit Health Promotion Charity registered with the Australian Charities and Not-for-profits Commission and under the Charitable Fundraising Act NSW, 1991.

These general purpose financial statements have been prepared in accordance with the requirements of the Australian Charities and Not-for-profits Commission Act 2012, Australian Accounting Standards – Reduced Disclosure Requirements and other authoritative pronouncements of the Australian Accounting Standards Board, and the Charitable Fundraising Act NSW, 1991.

The financial report was authorised for issue by the Board on 19 August 2020.

1. Significant accounting policies

Basis of preparation

The financial report is presented in Australian dollars which is the AGCMC's functional currency. The financial statements have been prepared on an accruals basis and are based on historical costs unless otherwise stated in the notes. The accounting policies that have been adopted in the preparation of this report are as follows.

(a) Revenue

Revenue recognition policy for revenue from contracts with customers (AASB 15)

AASB 15 15 requires revenue to be recognised when control of a promised good or service is passed to the customer at an amount which reflects the expected consideration.

The customer for these contracts is the fund provider. Revenue is recognised by applying a five-step model as follows:

- 1. Identify the contract with the customer
- 2. Identify the performance obligations
- 3. Determine the transaction price
- 4. Allocate the transaction price
- 5. Recognise recognition

Revenue is recognised under AASB 15 when the performance obligations in a service arrangement are sufficiently specific to identify satisfaction of those obligations. Under AASB 15 revenue is recognised when performance obligations are satisfied.

When amounts of income are received, other than investment income, that are not subject to specific performance obligations, they are generally recognised immediately in profit and loss under AASB 1058 Income of Not-for-profit Entities. Income streams recognised under AASB 15 will include membership fees, event charges, and certain sponsorships that are enforceable and with specific performance obligations.

Grant Funding

Grant income arising from an agreement which contains enforceable and sufficiently specific performance obligations is recognised when control of each performance obligations is satisfied. Such funds may be deferred as contract liabilities until recognised as income.

Within certain grant agreements there may be some performance obligations where control transfers at a point in time and others which have continuous transfer of control over the life of the contract.

Where control transfers at a point in time and others which have continuous transfer of control over the life of the control is transferred over time, generally the revenue is recognition based on either cost or time incurred which best reflects the transfer of control.

Notes to the financial statements (continued)

1. Significant accounting policies (continued)

Revenue recognition policy for revenue streams which are either not enforceable or do not have sufficiently specific performance obligations (AASB 1058)

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Grant income for which there are not sufficiently specific performance obligations is brought to account when received in accordance with AASB 1058.

Donations

Monetary and non-monetary donations are recognised as revenue when the Company gains control of the contribution or the right to receive the contribution. Non-monetary donations are recognised as revenue based on the fair value of the item.

(b) Interest income

Interest income is recognised in the statement of comprehensive income as it accrues, using the effective interest method.

(c) Expenditure

All expenditure is accounted for on an accruals basis.

(d) Income tax

No provision for income tax has been raised as the Entity is exempt from income tax under Div. 50 of the Income Tax Assessment Act 1997.

(e) Goods and services tax

Revenue, expenses and assets are recognised net of the amount of goods and services tax (GST), except where the amount of GST incurred is not recoverable from the taxation authority. In these circumstances, the GST is recognised as part of the cost of acquisition of the asset or as part of the expense.

Receivables and payables are stated with the amount of GST included. The net amount of GST recoverable from, or payable to, the ATO is included as a current asset or liability in the statement of financial position.

Cash flows are included in the statement of cash flows on a gross basis. The GST components of cash flows arising from investing and financing activities which are recoverable from, or payable to, the ATO are classified as operating cash flows.

(f) Cash and cash equivalents

Cash and cash equivalents comprise cash balances, cash on hand and short-term bills receivable.

(g) Impairment

The carrying amounts of assets are reviewed at each balance sheet date to determine whether there is any indication of impairment. If any such indication exists, the asset's recoverable amount is estimated. An impairment loss is recognised whenever the carrying amount of an asset exceeds its recoverable amount. Impairment losses are recognised in the statement of comprehensive income, unless an asset has previously been revalued, in which case the impairment loss is recognised as a reversal to the extent of that previous revaluation with any excess recognised through profit or loss.



Notes to the financial statements (continued)

1. Significant accounting policies (continued)

(h) Financial instruments

Financial instruments are initially measured at cost on trade date, which includes transaction costs, when the related contractual rights or obligations exist. Subsequent to initial recognition, the Entity's financial instruments are measured as set out below.

Financial assets at fair value

Some financial assets of the Entity may be classified as financial assets at fair value through other comprehensive income. Unrealised gains and losses arising from changes in the fair value are taken directly to the equity. Realised gains and losses on the sale of investments are also shown in equity as part of the reserve. Fair value is determined based on current bid price for all quoted investments.

Financial assets measured at amortised cost

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market and are stated at amortised cost using the effective interest method.

Financial liabilities

Non-derivative financial liabilities are recognised at amortised cost, comprising original debt less principal payments and amortisation.

(i) Trade and other receivables

Trade and other receivables are stated at their amortised cost less impairment losses.

(j) Trade and other payables

Trade and other payables are stated at amortised cost.

(k) Critical accounting estimates and judgements

The Board Members evaluate estimates and judgments incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the Entity. Revisions to accounting estimates are recognised in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods. The effect of the change relating to the current period is recognised as income or expense in the current period. The effect, if any, on future periods is recognised as income or expense in those future periods



Notes to the financial statements (continued

1. Significant accounting policies (continued)

(I) New and revised accounting standards

A number of new and revised standards became effective for the first time for the Company for accounting periods beginning on 1 July 2019, as described below.

AASB 15 Revenue from Contracts with Customers, AASB 1058 Income of NFP Entities

The Company has adopted AASB 15 Revenue from Contracts with Customers and AASB 1058 Income of Not for- Profit Entities for the first time in the current year with a date of initial application of years beginning 1 July 2019.

11

The Company has applied AASB 15 and AASB 1058 using the modified retrospective (cumulative catch-up) method which means the comparative information has not been restated and continues to be reported under AASB 118 Revenue, AASB 1004 Contributions and related interpretations. The following practical expedients have been applied on transition to AASB 15 and AASB 1058: For contracts modified prior to 1 July 2019, the Company has elected not to restate the contract for the modifications and has instead reflected the aggregate effect of all the modifications that occur before the transition date on 1 July 2019. There has not been a material change in the accounting of the revenue and income of the Company.

AASB 16 Leases

AASB 16 Leases became applicable for the Company in the current year. Under AASB 16, there is now no differentiation between finance and operating leases for the lessee and therefore all leases which meet the definition of a lease are recognised on the statement of financial position (except where an exemption election is used). When AASB 16 is applicable to a Company, right of use assets and lease liabilities are recognised on the balance sheet. The Company is not party to any leases and hence there are in impacts on the Company from the application of AASB 16.

(m) New accounting standards and interpretations

The AASB has issued new and amended Accounting Standards and Interpretations that have mandatory application dates for future reporting periods. The Entity has decided against early adoption of new and amended Accounting Standards and Interpretations that have mandatory application dates for future reporting periods.



Notes to the financial statements (continued)

		2020 \$	2019 \$
		¥	¥
2.	Revenue from operations		
	Government funding	10,000,000	10,000,000
	Funding and grants from corporate and institutional funding bodies	681,449	-
	Other revenue	23,877	-
	Total revenue from operations	10,705,326	10,000,000
3.	Service provider and projects expenses		
	Amounts paid or distributed to service providers for projects	8,304,750	750,000
	Total paid or provided.	8,304,750	750,000
4.	Consulting and support services expenses		
	Consulting and administration	424,919	215,817
	Legal costs	20,831	69,146
	Other costs	63,752	5,004
	Total professional services costs	509,502	289,967
5.	Cash and cash equivalents		
	Cash at Bank	12,967,029	8,910,102
6.	Prepayments		
	Prepayments		577
7.	Receivables		
	ATO receivable	228,476	69,582
	Other receivable	16,500	-
		244,976	69,582



Notes to the financial statements (continued)

	2020	2019
	\$	\$
8. Trade payables and accruals		
Trade and other payables	164	58,667
Credit card payable	-	3,135
Accruals	130,518	-
	130,682	61,802
9. Accumulated funds		
Accumulated funds at the beginning of the financial year	8,918,459	-
Surplus for the year	1,672,612	8,918,459
Accumulated funds at the end of the financial year	10,591,071	8,918,459
10. Reconciliation of cash flows from operating activities		
Surplus for the year	1,672,612	8,918,459
Changes in assets and liabilities		
Change in prepayments	577	(577)
Change in other assets	(175,394)	(69,582)
Change in accrued income	(9,748)	-
Change in contract liability	2,500,000	-
Change in trade and other payables	68,880	61,802
Cash flows from operating activities	4,056,927	8,910,102

13

11. Contingencies

Nil.

12. Commitments

The Company is contracted to fund certain projects with service providers. These agreements are entered into in accordance with the Company's funding support from Government and other entities to financially support and facilitate its core objectives.



Notes to the financial statements (continued)

13. Related party transactions

Key Management Personnel Compensation

The Company paid \$259,600 to key management personnel during the year. There were no other transactions with key management personnel during the year ended 30 June 2020. Key Management Personnel include Board members, the Chief Executive Officer (CEO) and the Deputy Chief Executive Officer. The Company's relationship with the CEO is governed by an Agreement for the Supply of Professional Services between the Company and the CEO, Professor David Thomas.

Non-executive Board members act in an honorary capacity and receive no compensation for their service. Board members may receive reimbursement for direct expenses they incur in meeting their duties as Directors. The CEO is also a Board member under the Company's constitution.

Other related party transactions

Board members of the Company may be Board members or executive level employees of entities with which this entity contracts, including as follows:

Garvan Institute of Medical Research is a member of this entity and appoints a Director to the Board under this Company's constitution. Professor Chris Goodnow is the appointed Director of this Company, by the Garvan Institute of Medical Research. CEO and Board member, Professor David Thomas is an executive level employee of Garvan Institute of Medical Research.

Garvan Institute of Medical Research has a multi-year Research Agreement with this Company. The Agreement encompasses the following transactions:

- Over 5 years, \$4,740,798 is payable for IT infrastructure, Personnel and Director and Clinical Cohorts. During the year, \$1,204,500 (2019: nil) was paid by this Company to Garvan Institute of Medical Research for these services.
- Over 5 years, an estimated \$10,688,500 is payable for screening and sequencing activities and a further \$3,771,375 for activities at other sites. These payments are contingent on contractual milestones being met by the service provider. During the year, \$2,693,625 (2019: nil) was paid by this Company to Garvan Institute of Medical Research for these activities.
- Over 5 years, \$955,645 is receivable as part of NSW Health funds allocated to support the establishment of a Business Development Office for this Company. During the year, \$200,000 (2019: nil) was received from Garvan Institute of Medical Research as part of this funding.

Under a Licence to Occupy Agreement between the two entities, Garvan Institute of Medical Research provides this Company access to a licensed area on a pro-bono basis.

The University of Sydney is a member of this entity and appoints a Director to the Board under this Company's constitution. John Simes is the appointed Director of this Company, by the University of Sydney. The University of Sydney is party to a multi-year Master Clinical Trial Research Agreement where \$6,981,514 is payable over six years. These payments are contingent on contractual milestones being met by the service provider. During the year, \$2,390,375 (2019: nil) was paid to that entity by this Company under this agreement.



Notes to the financial statements (continued)

13. Related party transactions (continued)

Richard Vines is Board member of this Company and also the Chief Executive Officer and Chairman of Rare Cancers Australia (a charity registered with the ACNC). Rare Cancers Australia is party to a multi-year service contract with this Company where \$4,500,000 is payable over four years. These payments are contingent on contractual milestones being met by the service provider. \$750,000 (2019: nil) was paid to that entity during the year.

15

The Members of this Company as a group appoint two Directors per this Company's constitution. Former Board Member, Clare Scott who resigned in December 2018 was one of the Members Nominating Group appointed Director of this Company. Clare Scott is also on the Board of BioGrid Australia Limited, an entity which is party to a multi-year research agreement with this Company where \$3,775,000 is payable over four years. These payments are contingent on contractual milestones being met by the service provider. During the year, this Company paid \$1,016,250 (2019: nil) to BioGrid Australia Limited as part of this agreement. Members of the Company may otherwise be entities which may be recipients of funding from this Company, in addition to the amounts disclosed in this Note regarding Related Party transactions in the current year,

Medicine Australia delegates, as a group, appoint a Director of this Company per this Company's constitution. Bruce Goodwin is the Medicine Australia Nominating Group appointed Director of this Company. Entities that may receive funding from this Company may be associated with Medicine Australia.

Australian Genomic Health Alliance delegates, as a group, appoint a Director of this Company per this Company's constitution. Kathryn North is the Australian Genomic Health Alliance Nominating Group appointed Director of this Company. Entities that may receive funding from this Company may be associated with Australian Genomic Health Alliance.

There were no other related party transactions during the year ended 30 June 2020.

14. Events subsequent to balance date

There are no other material events subsequent to balance date.

15. Entity details

The registered office of the Entity is L7 The Kinghorn Cancer Centre, 370 Victoria Street, Darlinghurst NSW, 2010. The company is limited by guarantee. Each Member undertakes to contribute an amount not exceeding \$10 to the property of the Company if the Company is wound up.

16. Disclosures in accordance with the Charitable Fundraising Act NSW, 1991.

The Company is registered under the Charitable Fundraising Act NSW, 1991 and is required to include details of fundraising activities and the application of funds from fundraising in its financial statements.

The company's revenue from operations, disclosed at Note 2, includes amounts received from nongovernment, corporate and institutional funders to be used and distributed for the charitable purposes for which the Company operates. No formal fundraising programmes have yet been developed or implemented by the Company. The application of the Company's funds is disclosed in the Statement of Profit and Loss and Other Comprehensive Income. The Statement of Financial Position indicates accumulated Funds held by the Company at year end for future use by the Company in its charitable purposes.



Declaration by the Principal Officer in accordance with the Charitable Fundraising Act 1991

I, Professor David Thomas, Chief Executive Officer of Australian Genomic Cancer Medicine Centre Limited, declare that in my opinion:

- a) the income statement of Australian Genomic Cancer Medicine Centre Limited for the financial year ended 30 June 2020 gives a true and fair view of all income and expenditure of the organisation with respect to fundraising appeals;
- b) the Statement of Financial Position of Australian Genomic Cancer Medicine Centre Limited as at 30 June 2020 gives a true and fair view of the state of affairs of the organisation with respect to fundraising appeals conducted by the Company;
- c) the provisions of the Charitable Fundraising Act 1991, the Regulations under that Act and the conditions attached to the Charitable Fundraising Authority held by the Company have been complied with by the Company during the year ended 30 June 2020; and
- d) the internal controls exercised by Australian Genomic Cancer Medicine Centre Limited are appropriate and effective in accounting for all income received and applied by the organisation from any of its fundraising appeals during the year ended 30 June 2020.

Professor David Thomas Chief Executive Officer

Sydney

19 August 2020

Responsible Entities' Declaration

The Responsible Entities of Australian Genomic Cancer Medicine Centre Limited (AGCMC) declare that:

- The financial statements of AGCMC are in accordance with the Australian Charities and Not-forprofits Commission Act 2012 including:
 - giving a true and fair view of its financial position as at 30 June 2020 and of its performance for the financial year ended on that date;
 - complying with Australian Accounting Standards Reduced Disclosure Requirements and the Australian Charities and Not-for-profits Commission Regulation 2013; and
- There are reasonable grounds to believe that AGCMC will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Board:

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Paul Jeans Chair of the Board of Directors

Sydney

19 August 2020

Bruce Goodwin Director



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18

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Auditor's Independence Declaration

To the Responsible Entities of Australian Genomic Cancer Medicine Centre Limited

In accordance with the requirements of section 60-40 of the Australian Charities and Not-for-profits Commission Act 2012, as lead auditor for the audit of Australian Genomic Cancer Medicine Centre Limited for the year ended 30 June 2020, I declare that, to the best of my knowledge and belief, there have been no contraventions of any applicable code of professional conduct in relation to the audit.

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Grant Thornton Audit Pty Ltd Chartered Accountants

Jama. Wate.

James Winter Partner – Audit & Assurance

Sydney, 19 August 2020

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Independent Auditor's Report

To the Members of Australian Genomic Cancer Medicine Centre Limited

Report on the audit of the financial report

Opinion

We have audited the financial report of Australian Genomic Cancer Medicine Centre Limited (the "Registered Entity"), which comprises the statement of financial position as at 30 June 2020, and the statement of profit or loss and other comprehensive income, statement of changes in funds and statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies and the Responsible Entities' declaration.

In our opinion:

- the financial report of Australian Genomic Cancer Medicine Centre Limited has been prepared in accordance with the requirements of Division 60 of the Australian Charities and Not-for-profits Commission Act 2012 ("ACNC Act "), including:
 - a) giving a true and fair view of the Registered Entity's financial position as at 30 June 2020 and of its financial performance for the year then ended; and
 - b) complying with Australian Accounting Standards and Division 60 of the Australian Charities and Not-for-profits Commission Regulation 2013; and
- 2. the financial report of Australian Genomic Cancer Medicine Centre Limited shows a true and fair view of the financial result of its fundraising appeals for the year ended 30 June 2020;
- the financial report and associated records of Australian Genomic Cancer Medicine Centre Limited have been properly kept during the year ended 30 June 2020 by the Registered Entity in accordance with the Charitable Fundraising Act 1991 and Regulations 2015;
- money received as a result of fundraising appeals conducted during the year ended 30 June 2020 by Australian Genomic Cancer Medicine Centre Limited has been properly accounted for and applied in accordance with the Charitable Fundraising Act (NSW) 1991 and Regulations 2015; and
- 5. there are reasonable grounds to believe that Australian Genomic Cancer Medicine Centre Limited will be able to pay its debts as and when they fall due.

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5.4 Liability limited by a scheme approved under Professional Standards Legislation.



Basis for opinion

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Registered Entity in accordance with the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants* (the Code) that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of the Responsible Entities for the financial report

The Responsible Entities of the Registered Entity are responsible for the preparation and fair presentation of the financial report in accordance with Australian Accounting Standards, the ACNC Act and the Charitable Fundraising Act (NSW) 1991, and for such internal control as the Responsible Entities determine is necessary to enable the preparation of the financial report that is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the Responsible Entities are responsible for assessing the Registered Entity's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Responsible Entities either intend to liquidate the Registered Entity or to cease operations, or have no realistic alternative but to do so.

The Responsible Entities are responsible for overseeing the Registered Entity's financial reporting process.

Auditor's responsibilities for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

As part of an audit in accordance with the Australian Auditing Standards, we exercise professional judgement and maintain professional scepticism throughout the audit.

We also:

- Identify and assess the risks of material misstatement of the financial report, whether due to fraud or error, design and
 perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to
 provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for
 one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the
 override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Registered Entity's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Registered Entity.



- Conclude on the appropriateness of the Registered Entities' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Registered Entity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial report or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Registered Entity to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial report, including the disclosures, and whether the financial report represents the underlying transactions and events in a manner that achieves fair presentation.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Grand Thorndon.

Grant Thornton Audit Pty Ltd Chartered Accountants

ama. Wale

James Winter Partner – Audit & Assurance Sydney, 19 August 2020





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