Outsmarting cancer, together

Annual Report 2021

Omico.

2019/2020 highlights at a glance

MoST patients screened

at September 2020: 2812

at September 2021: 3759

MoST patients on novel therapy studies

at September 2020: 201

at September 2021: 309

MoST subprograms

- pan cancer
- lung cancer
- blood cancer
- pancreatic cancer

MoST recruiting sites

- 6 member sites
- 15 other sites across Australia (plus NZ)

MoST patients receiving a matched therapy after molecular screening

461 (14.3%)

MoST substudies

at September 2020: 3 recruiting; 10 in start up

at September 2021: 1 closed; 1 in follow-up; 12 recruiting; 8 in start up

RisC participants enrolled

at September 2020: 1316

at September 2021: 1532

Pharmaceutical industry MoST support

$16.7m

in-kind support: drugs to treat 868 patients

Philanthropic support for MoST substudies

$3.6m

SMOC+ participants enrolled

at September 2020: 91

at September 2021: 117

SMOC+ cancer detection

32 new primary cancers in 23 (20%) individuals

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

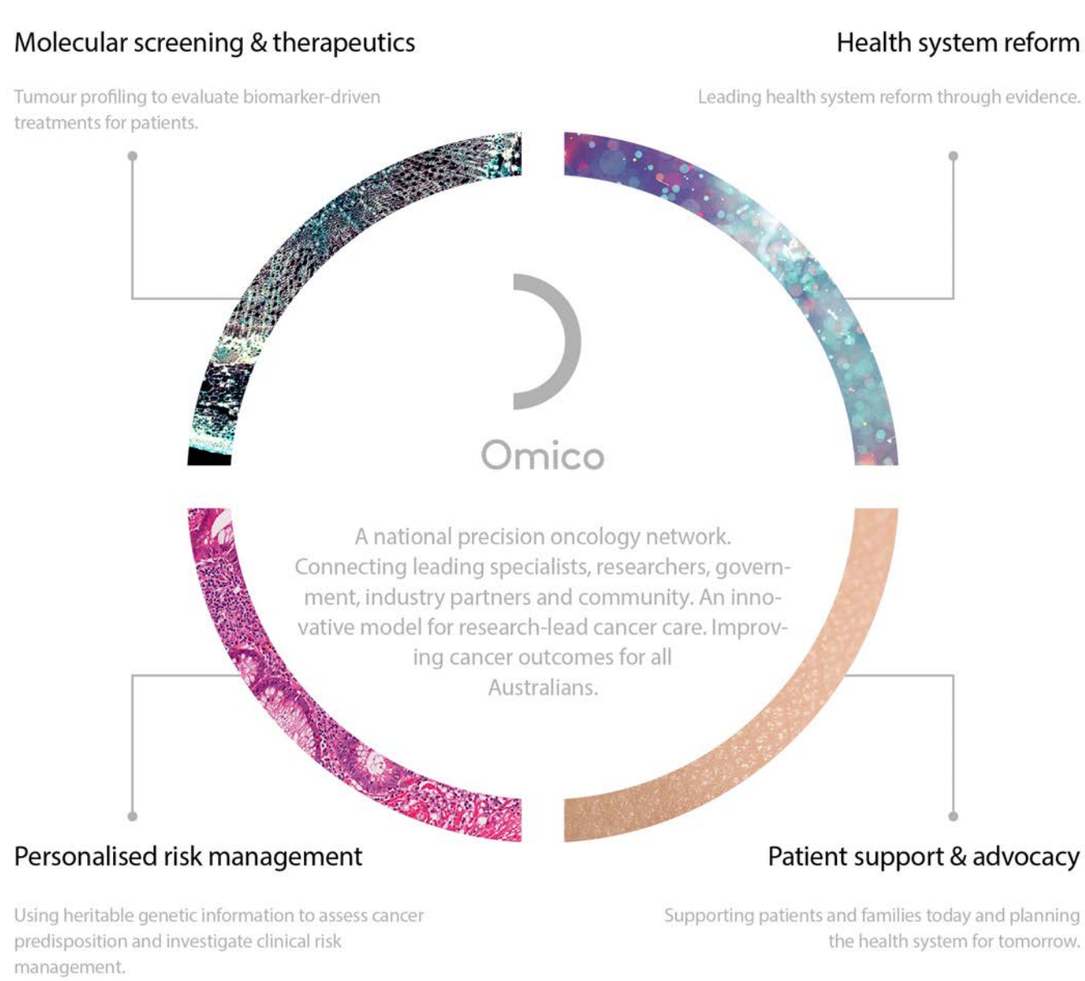
Omico will improve outcomes for Australians with cancer by accelerating the use of precision oncology as a research-led model of care, growing the clinical trials industry and modernizing the Australian healthcare system.

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



Our board

Mr Paul Jeans

Chancellor, University of

Mr Richard Vines

(Deputy Chair)*

Professor David Thomas

(CEO)*

Ms Sue MacLeman

Professor Chris Goodnow (Garvan Institute of Medical Research)

Mr Bruce Goodwin

(for Medicines Australia)*

Professor John Simes

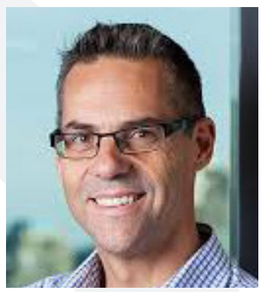
(for University of Sydney)

Professor Kathryn North AC

(for Australian Genomic Health

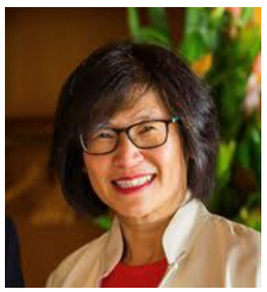
Professor Michael Brown

(Member representative)

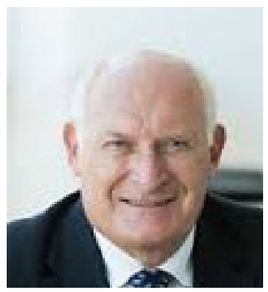


Professor Ricky Johnstone

(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

Dr Vera Terry

Deputy CEO

Mr Satish Nair

CFO

Dr Mandy Ballinger

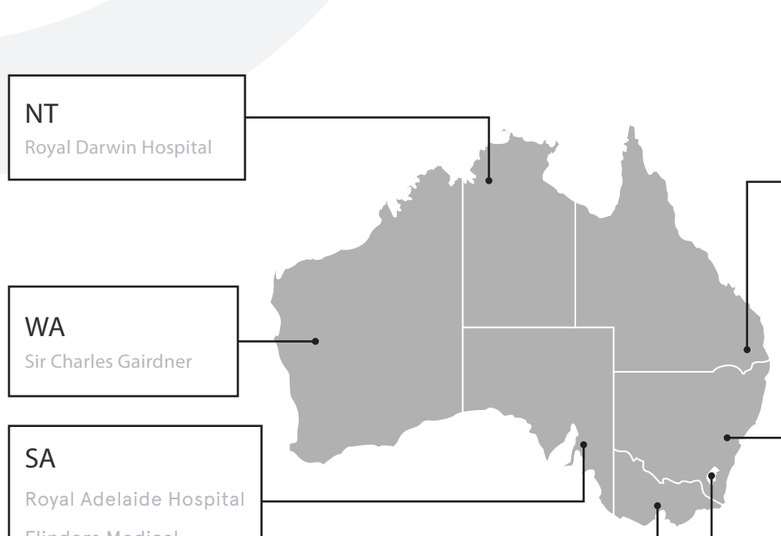
Head of Cohorts

Dr Lucille Sebastian

Program Manager

Our network

Omico is a network of leading cancer treatment centres, hospitals, and academic and medical institutions, located in every State and Territory around the nation.



NT
Royal Darwin Hospital

WA
Sir Charles Gairdner

SA
Royal Adelaide Hospital
Flinders Medical Centre

VIC
Peter MacCallum Cancer Centre
Alfred Hospital
St Vincent's Hospital (Melb)
Oliva Newton John Cancer Centre

QLD
Princess Alexandra Hospital
Royal Brisbane Hospital
Prince Charles hospital

NSW
The Kinghorn Cancer Centre
Chris O'Brien Lifehouse
St George Hospital
Westmead Hospital
Wollongong Hospital
Liverpool Hospital
Royal North Shore Hospital
Border Medical Oncology

ACT
Canberra Hospital

TAS
Royal Hobart Hospital

New Zealand
Auckland Hospital

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.

Members

linear
PathWest
In partnership with Northern Territory Government
Peter Mac — Peter MacCallum Cancer Centre Victoria Australia
SA Pathology
Government of South Australia — Health Central Adelaide Local Health Network
pathology queensland
Metro South Health — Queensland Government — RHH
The University of Sydney
Garvan Institute of Medical Research
NHMRC Clinical Trials Centre

Industry Partners

AstraZeneca
Pfizer Oncology
Bayer
Roche
Lilly
BeiGene
Foundation Medicine
Medicines Australia
illumina
Eisai
Sun Pharma
Seagen

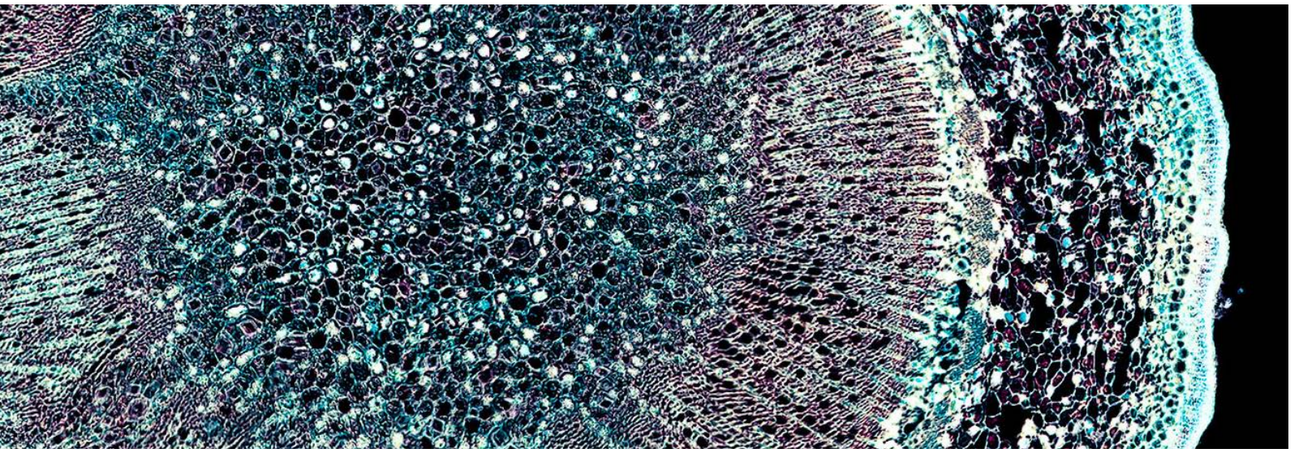
International molecular profiling studies

ASCO Tapur (USA)
CAPTUR (Canada)
DRUP (Netherlands)

Collaborators

rare cancers Australia
BioGrid — Connecting health information
Macquarie University — Sydney · Australia
NSW Government Health
NSW Government Health Pathology
Australian Genomics Health Alliance
canteen
The George Institute for Global Health
QIMR Berghofer Medical Research Institute
Leukaemia Foundation
Minderoo Foundation
Douglass Hanly Moir Pathology — Quality is in our DNA
CRBF — Cooper Rice-Brading Foundation
Australian Government Department of Health

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 Not-for-profits Commission (ACNC).

> A not for profit company, limited by guarantee

The Objectives of Omico are to:

1. expand the Molecular Screening and Therapeutics (MoST) and Cancer Risk in the Young (RisC and SMOC+) Programs;
2. 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;
5. support the collection, maintainence and access to clinical data via national, linked rare cancer registries;
6. promote a managed, cooperative and networked approach nationally to research and education between cancer centres so as to maximise the benefits from that research;
7. 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;
8. 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;
9. 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
11. secure funding for Omico activities 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.

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)

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)

Report from the Chair of the Board and the CEO

Dear Colleagues

2021 has been another big year for Omico, and the second under the shadow of COVID-19. If anything, it is noteworthy that our activities have significantly expanded, despite the competing demands on our health system. In 2021, we reached our original 5 year milestone for screening on MoST (3095 participants), with another 3 years to run. We're pleased to report that we have now opened at 21 cancer centres around Australia. MoST is now open in Auckland as well, marking an important step to regional leadership. More than 400 individuals enrolled to date on MoST have gone on to receive a matched therapy, either on MoST trials or those of our collaborators, or other trials recruiting across Australia. The number of MoST trials open to recruitment matured in 2021, and as of the time of writing, we have either open or in late development more than 900 patients' worth of clinical trials. We'd like to single out the NHMRC Clinical Trials Centre for their hard work in this achievement. We have also diversified our trials portfolio. These trials now comprise 3 groups: our core trials (C1), which are wholly run through MoST; collaborative (C2) trials, which are trials run in partnership with other clinical trials centres; and company-sponsored trials (C3), which are trials being run by industry, but for which molecular screening is critical.

It is worth specifically noting some of the highlights of clinical trials activity. This year ASPiRATION, our lung cancer subprogram, opened to accrual, having recruited more than 120 of a total of 1,000 participants. Already the results of screening appear striking—we are looking forward to the data maturing over the next 2 years. In addition, our haematology subprogram, MoST-LLy, opened to accrual in August 2021. We are delighted to report a new subprogram in pancreatic cancer was successful in attracting funding from Cancer Institute New South Wales, and we expect the first trials under this program to open by the end of this year. In addition to individual trials and our focused subprograms, we also report a new partnership with Professors Cebon and Klein from the Olivia Newton John Cancer Research Institute, for our first C2 trial: MoST-CIRCUIT. With the support of Bristol-Myer Squibb and the Minderoo Foundation, MoST-CIRCUIT offers doublet immunotherapy for 240 patients with advanced rare cancers. MoST-CIRCUIT opened to enrolment in September this year, and has begun brightly.

Our long-term follow up unit has begun to track clinical outcomes for patients on MoST. Although the data are young, we can clearly see many patients have experienced clinical benefit. For those with the best matching therapies, survival appears almost doubled. Some patients with advanced cancers with no standard therapy options have had complete radiologic responses from treatments available through trials of new drugs. We are gathering solid data on these outcomes currently. Another important achievement this year was the creation by Dr Frank Lin and colleagues of a software algorithm that systematically matches genomic profiles against a comprehensive map of existing targeted therapy trials in Australia, massively increasing the 'actionability' of screening.

Our personalised risk management programs, RisC and SMOC+, continue steady enrolment. There are two highlights in the 'risk' space. First, a major study is currently under review concerning new methods of detecting genes implicated in cancer risk, which included patients from the RisC study. We expect this paper to be published late in 2021, or early 2022. Second, and even more important, Dr Ballinger and colleagues have embarked on a submission to the Federal government for a medical benefits scheme item number for whole-body MRI scanning for early cancer detection. We expect to hear the outcome of this application in 2022. In the interval, with strong support from the paediatric cancer community, Dr Ballinger has expanded SMOC+, our whole-body MRI study, to cover children with increased cancer risk.

More broadly, the board of Omico has been working hard on our long-term sustainability. In 2021, we have put to the Federal government a proposal to form a public:private consortium to expand access to both genomic screening and clinical trials to more than 27,000 Australians by 2024. This proposal was made possible through Omico's progressive engagement with industry, both large and small. We would like to single out Dr Vera Terry and Mr Satish Nair for their contributions to the DISER submission. After an initial pre-budget submission for universal coverage was unsuccessful, we were advised to pursue an opportunity via the Department of Industry, Science, Energy and Resources (DISER), rather than through Health. The transition from medical research to a sustainable model in partnership with industry is critical to sustainable access to research-led care, for Australian medical research in general, and for patients with cancer in particular. Amongst all fields of medicine, we believe oncology is 'shovel-ready' to make the transition from research to a new model of care, and that Omico has a responsibility to take this major step.

Other activities of note in 2021 include Rare Cancers Australia under Richard and Kate Vines, who have provided both support for many patients and their families as they battle cancer, but have also continued their advocacy at the highest levels for our collective cause. The rare cancers portal has also begun to gather momentum in 2021, with more than 500 referrals of patients to date. The provision of expert advice on rare cancers for many patients represents a new service to the community, with good reports. Research activities are beginning to yield fruit, with more than 70 publications to date, and more to come over the next 2 years. Omico believes in research-led, evidence-based care: these papers are the tangible expression of that commitment.

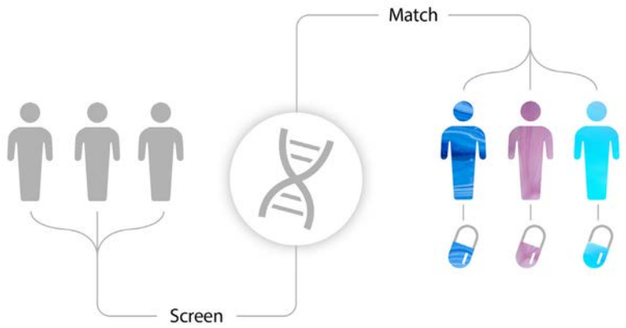
In 2021, the board farewelled its founding Chair, Professor Mark Wainwright. Mark has left Omico with sound foundations, and in an excellent position to take the important next steps towards a sustainable future. We thank him for his service. The board also welcomes Dr Sue MacLeman as our newest Director. Sue comes with an outstanding record as Chair of MTP Connect, and in the medtech sector more generally. Financially, Omico is in an excellent financial position to deliver on its expanded portfolio of commitments. We acknowledge with gratitude the support we have received from our Finance Risk and Audit committee, chaired by Mr Bruce Goodwin, with the support of Tze Masters and Richard Vines.

We look forward to 2022, continuing the expansion of our current activities, and new ones as time and resources permit. We expect a significant expansion of Omico's administrative core, to deliver an increasingly large, rich and complex agenda. We thank the Board and Executive who will continue to work closely together on our vision to bring the promise of genomic technologies to improve the lives of individuals and families affected by cancer. We'd also like to thank our brilliant network of co-investigators and industry and academic partners for their universal commitment to our program of work. Finally, we'd like to acknowledge the patients and their families, who provide us with our ultimate purpose.

Mr Paul Jeans (Chair of the Omico Board)

Professor David Thomas (CEO)

Molecular Screening and Therapeutics Program (MoST)



After 5 years of operation, the MoST Program has become the leading national program delivering molecular screening and trials matching to advanced cancer patients.

The last 12 months under COVID-19 have continued to challenge the 'business as usual' paradigm but highlight the ongoing commitment of our national network.

Recruitment to the screening component of the Molecular Screening and Therapeutics (MoST) program continues to be stable and is still exceeding expectations.

> MoST - Using molecular profiling to find biomarkers to guide therapy options

During 2021 we have continued to expand and evolve the MoST screening platform to accommodate additional histopathology specific cancer groupings to the pan cancer cohort. Following on from establishment of the blood and lung cancers cohorts, we have included a pancreatic cancer group.

Pancreatic cancer is the fifth most common cause of cancer death over all, with survival rates that haven't really improved over the past 40 years.

It is estimated that 4261 new cases of pancreatic cancer will be diagnosed in Australia in 2021. Unfortunately, early-stage pancreatic cancer rarely causes signs or symptoms, which can make it hard to diagnose. Symptoms often only appear once the cancer is large enough to affect nearby organs or has spread.

The expansion into blood, lung and pancreas specific cancers leverages the MoST screening infrastructure established with support of the federal and state governments in collaboration with industry.

The ASPiRATION study in collaboration with industry and the Thoracic Oncology Group of Australasia (TOGA), 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 started recruiting patients in January 2021.

The Leukaemia Foundation and Tour de Cure are supporting the MoST-LLy pilot that provides molecular screening for up to 240 leukaemia or lymphoma patients and access to innovative clinical trials for up to 32 of those patients. The MoST-LLy team has been successful in attracting MRFF funding to increase the number of patients to be screened (up to an additional 240 patients) and develop an additional clinical trial.

> Expanding to incorporate subprograms in blood, lung and pancreas cancer

MoST-LLy started recruiting patients in August 2021.

MoST-Pancreas has been established with funding from the Cancer Institute of NSW. The grant supports the establishment of a long-term prospective national cohort of over 400 advanced pancreatic patients and enrol up to 100 patients into 2 focussed clinical trials.

The framework protocol underpinning the MoST program has also changed to accommodate other changes in the program. For example, we have incorporated 'reflex testing' where there is insufficient biopsy tissue for screening.

These subprograms leverage the capacity of the screening infrastructure under the MoST program. Patients recruited to ASPiRATION and MoST-LLY are in addition to the 3095 patients under the Commonwealth grant. The pancreatic cancer cohort patients are identified from within the current MoST screened cohort.

Patient recruitment to MoST sub-studies has seen a significant uplift - 108 patients enrolled into MoST substudies between September 2020 and September 2021, bringing the total to 309. This uplift has been achieved through the opening of an additional 7 substudies.

Over the past year we have also developed novel partnerships that have resulted in expanded treatment options being made available to MoST screened patients.

We now have 3 categories of studies that are supported by the MoST screening infrastructure.

MoST Core Studies (C1) - these are the substudies developed under the MoST Framework protocol and delivered by the NHMRC CTC at the University of Sydney.

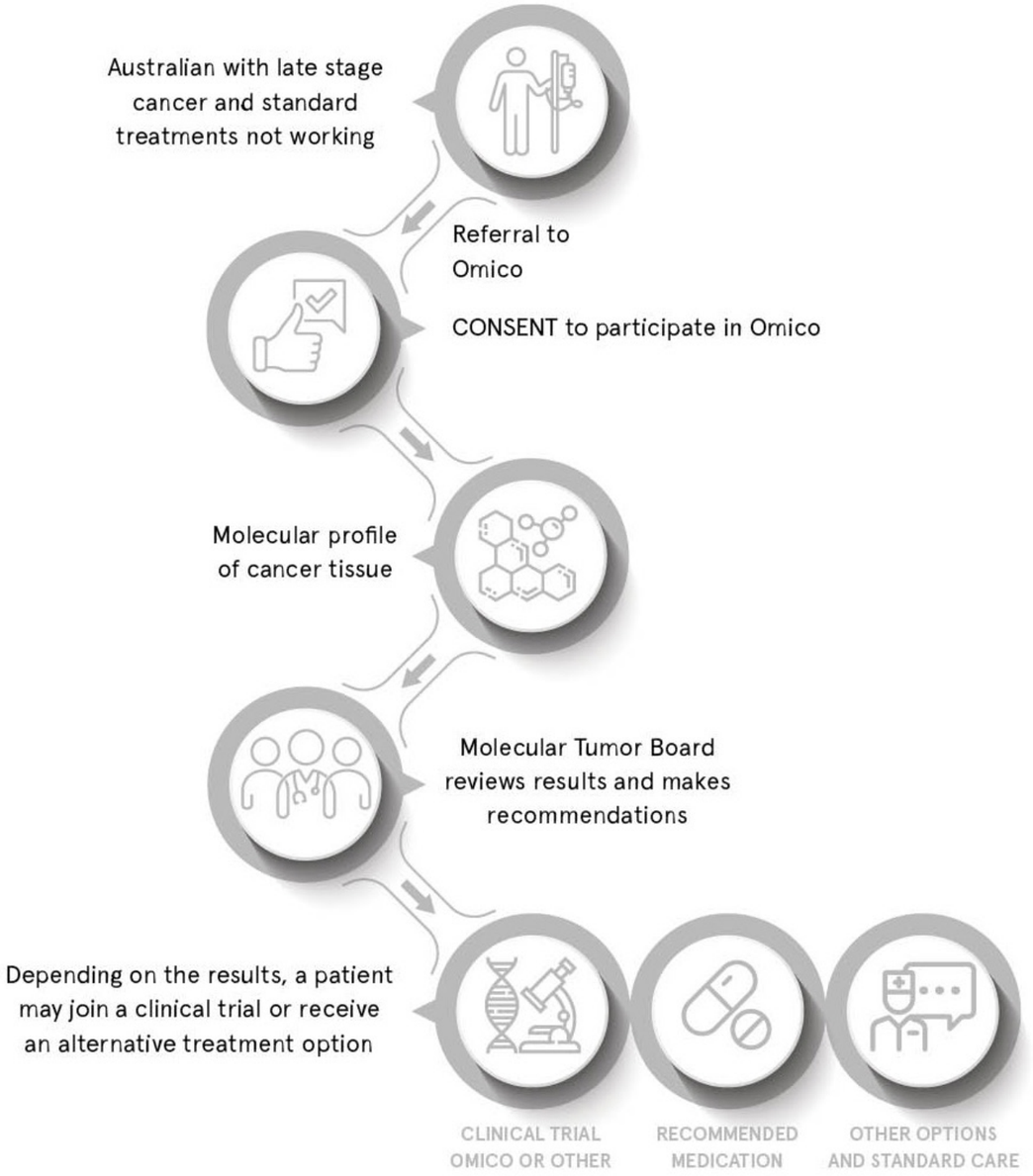
MoST Companion Studies (C2) - these studies are collaborations between Omico and other groups or organisations that leverage the MoST screening program and complement the therapeutics program. For example, MoST CIRCUIT - a collaboration with the Olivia Newton John Cancer Research Centre (ONJCRI) on an immunotherapy clinical trial. This companion study will recruit up to 240 patients from the MoST screening program. The MoST-Pancreas substudies are also companion studies that will be deliver by The George Institute on behalf of Omico.

MoST Company Studies (C3) - are studies sponsored by industry partners. These studies are complementary to the MoST therapeutics program and leverage the screened cohort by providing focussed treatment recommendations based on selected biomarkers in rare populations.

Our trials expansion strategy to include MoST Companion and Company trials is now underway and will provide treatment options to at least 1000 patients.

> More treatment options for patients:
>
> C1, C2 and C3 studies

Patient Pathway



MoST screening update

MoST pan cancer cohort screening update:

In total, over **3759** patients have been enrolled into the screening program since 2016.

Patients with a broad range of cancer morphologies have been enrolled into the screening program - more than 75% with rare cancers, 4% less common cancers and 21% with common cancers. Almost 22% of patients are currently referred from outside NSW.

ASPiRATION lung cancer cohort:

1000 metastatic non-small cell lung cancer patients are to be recruited to the ASPiRATION subprogram by the end of 2023. After a delayed start due to COVID-19, **122** patients had been enrolled into the cohort. These patients represent an additional 1000 individuals that will access comprehensive genomic profiling (CGP) or molecular profiling for their cancer.

Leukaemia/Lymphoma (MoST-LLY) cohort screening update:

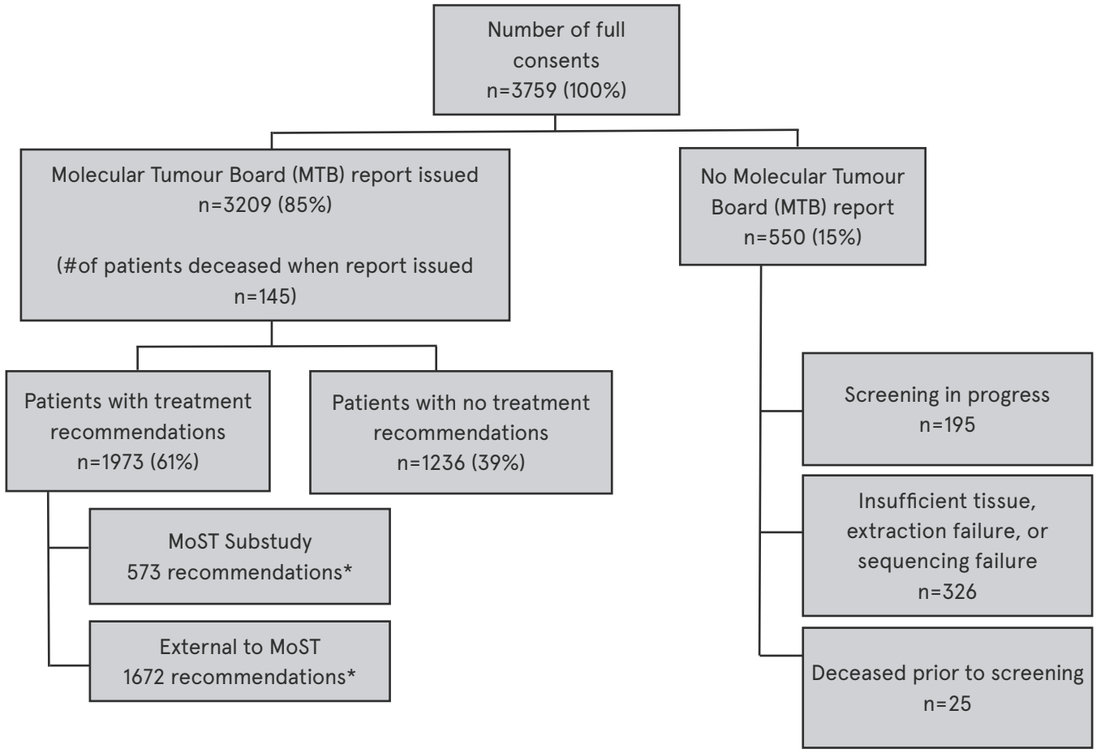
Founding support from the Leukaemia Foundation, Tour de Cure and the MRFF provide an additional 480 patients access to molecular profiling for their blood cancer. Recruitment started in August 2021.

ASPiRATION and MoST-LLY patients enrolled in MoST by state

State	ASPiRATION	MoST-LLY
NSW	59	
ACT		
VIC	28	
TAS	11	
SA	4	
WA	15	
NT		
QLD	5	4
Total	122	4

Pan cancer patients enrolled in MoST by state (mid-September 2021)

About the MoST pan cancer cohort:



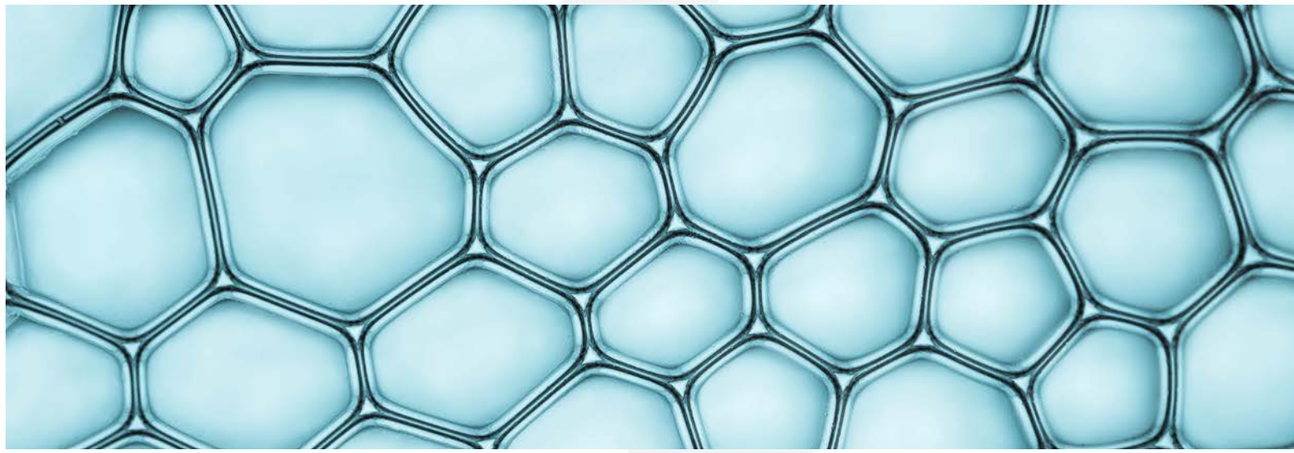
Of the 3759 patients enrolled, 3209 (85%) have had an MTB report issued. 1784/3759 (47%) patients are deceased, with 170/1784 (10%) deceased prior to the completion of molecular screening.

Treatment recommendations have been made to 1916 patients.

Note:

*some patients had more than one treatment recommendation and may be counted more than once.

MoST therapeutics update



The broader MoST substudy pipeline (C1, C2 and C3) has increased the pace of study activity at our sites. The NHMRC CTC at the University of Sydney, (working on substudies in 3 subprograms - pan cancer, blood cancer and first line lung cancer), has undertaken nearly 100 site initiation visits across 9 substudies. Four ASPiRATION associated therapeutic substudies are open to recruitment. The MoST-LLy blood cancer subprogram is open to recruitment with a treatment substudy open for enrolment and a second substudy in start up.

> Substudy update:
>
> 1 closed
> 1 in follow-up
> 12 recruiting
> 8 in start up

Two MoST-Pancreas substudies are being developed in collaboration with The George Institute of Global Health, and are well underway to open by the end of 2021.

The Clinical Trial Working Group (CTWG) continues to expand with representation and deeper engagement from state and territory members, subprogram leadership and a growing group of research fellows. Regular meetings take place to review concepts, brain storm potential new ideas and review trial progress.

MoST core substudies (C1): the capacity to deliver treatment through the MoST substudies increased through 2021. As at September 2021, there were:

- 5 active molecular screening centres, with participating sites in all states and territories recruiting to the screening program.
- an increased number of centres offering treatment for substudies, especially sites focusing on the subprogram expertise in lung, blood and pancreatic cancers.
- 21 sites across the country engaged with the therapeutics program. The number of sites is increasing as interest in the program continues to build, including expansion to New Zealand.

During 2021, the novel partnerships developed by Omico have resulted in expanded treatment options being made available to MoST screened patients (C2 and C3 studies).

MoST companion studies (C2) include:

- MoST CIRCUIT - (Combination Immunotherapy for Rare Cancers

- Under investigation) an immunotherapy clinical trial sponsored by Olivia Newton John Cancer Research Centre, with support from Bristol-Myers Squibb Ltd, the Minderoo Foundation and Omico. This study will provide treatment options for up to 240 MoST screened patients
- MoST Porcupine2 – a company supported clinical trial for pancreatic cancer patients, sponsored in Australia by Omico in collaboration with The George Institute.
- SPEAR – a pancreatic cancer patient trial, funded by Cancer Institute of NSW and sponsored by Omico in collaboration with The George Institute

MoST Company studies (C3) include:

- Libretto 431 – patients identified as carrying a RET mutation
- Teliso V – patients identified with cMET amplification or mutation

Over the past year there has been an increase in the number of concepts and proposals that have attracted grant funding and 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 genomic research, clinical trials, translational research, business development and industry partnerships.

The existence of the MoST infrastructure is a powerful endorsement of the acceptance by the patients, clinicians, industry partners and granting bodies, of molecular profiling in the advanced cancer setting.

Total enrolment onto sub-studies to September 2021: **309 patients.**

Current study pipeline status:

MoST Substudies (C1) in recruitment or follow-up:		Status	Recruitment/target
2+	Durvalumab and Tremelimumab (pan cancer)	closed	49/49
4	Vismodegib (pan cancer)	recruiting	11/16
5	Eribulin (pan cancer)	in treatment and follow up	16/16
6	Larotrectinib (pan cancer)	recruiting	1/32
7	Tremelimumab (pan cancer)	recruiting	7/48
8	Trastuzumab emtansine (Kadcyla) (pan cancer)	recruiting	30/32
8+	Trastuzumab emtansine (Kadcyla) (ASPiRATION)	recruiting	2/32
10	Palbociclib plus avelumab (pan cancer)	recruiting	25/32
11	Tildrakizumab (pan cancer)	recruiting	25/32
12	Vemurafinib and cobimetinib (combined pan cancer and ASPiRATION)	recruiting	4/64
13	Entrectinib (combined pan cancer and ASPiRATION)	recruiting	0/16
14	Alectinib (pan cancer and ASPiRATION)	recruiting	1/16
15	Acalabrutinib plus durvalumab (blood)	recruiting	1/32
MoST Substudies (C1) in start up			Target number
9	Tucatinib and trastuzumab (pan cancer)		32
16	Pamiparib (blood)		16
17	Tepotinib (ASPiRATION)		32
18	Durvalumab plus chemotherapy (pan cancer)		16
19	Sotorasib (AMG510) (pan cancer)		32
20	Seribantumab (pan cancer)		16
MoST Companion studies (C2)			Redcruitment/Target number
1.	MoST CIRCUIT	recruiting	7/240
2.	MoST Porcupine2	in Start up	8
3.	SPEAR	in start up	32
MoST Company studies (C3)			Target number
1.	LIbretto 431	referring	20
2.	Teliso V	referring	8
		Total potential recruitment numbers to date	868

MoST long-term follow-up unit (LTFU)

The long-term follow-up unit (LTFU) continues to collect information about patients at a number of time points throughout their cancer journey.

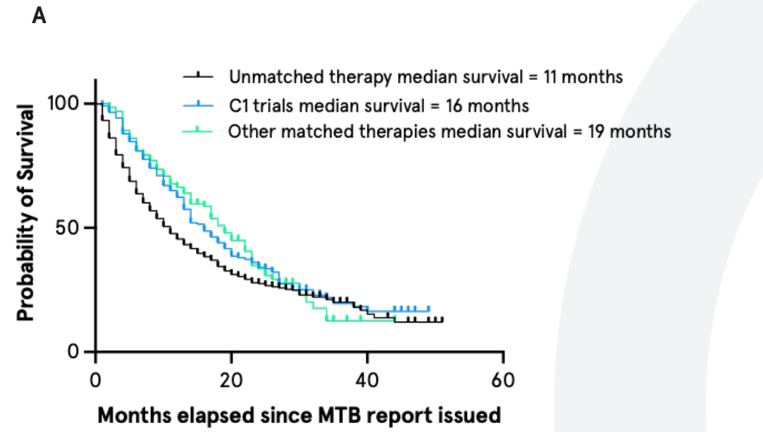
The LTFU is working with remote (secure) data collection instruments to supplement the more traditional methods of data collection e.g. phone, fax and email. This has meant that COVID-19 has had little effect on progress, but has allowed improvements in process.

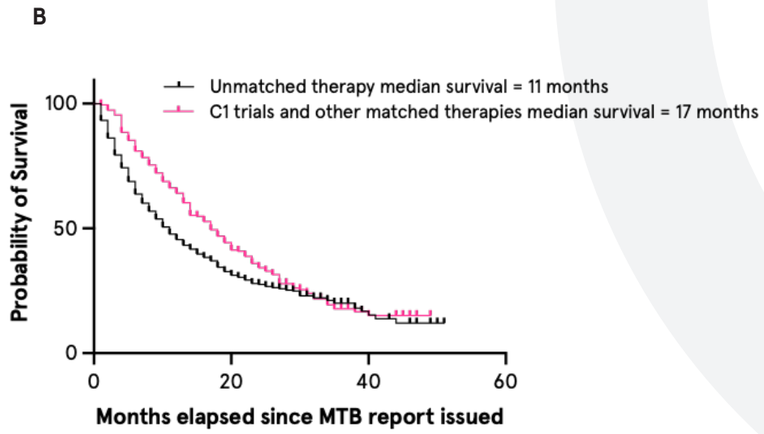
> 89% of patients (2409 out of 2711) have at least one time point follow up completed

Patient follow-up remains at the fore-front of the program and allows the capture of information that might better predict benefit from molecular screening.

Data collection to date:

- Clinical follow up has been prioritised for 2711 patients with at least one follow up time point completed for 2409 patients (89%). We are aiming for at least 80% completion rate acknowledging the challenges to collecting information when patients have been referred from over 160 clinics nationally
- Overall survival (date of death) has been collected for 1504 (62.4%) of the patients with follow up
- Patient reported quality of life (EQ-5D-5L) is being collected 6 monthly on all patients
- Patient reported performance status (ECOG) has been collected 6 weekly via a patient newsletter in a pilot study to assess feasibility. This has proven successful and will be expanded across the entire MoST cohort.





Preliminary results indicate that molecular screening provides benefit for patients

- 3209 patients have had an MTB report issued.
- 472 patients (17.4%) were deceased prior to or within 8 weeks of the MTB report being issued and were likely too unwell to benefit from molecular screening.
- 263 patients (8.2%) have been enrolled onto a MoST signal seeking C1 clinical trial as a direct result of MoST molecular screening with the median survival of this cohort 16 months (Fig A).
- An additional 198 patients (6.2%) have received a matched therapy due to a clinical decision as a direct result of MoST molecular screening with the median survival of this cohort 19 months (Fig A).
- These therapies have been accessed via other clinical trials (34%), compassionate access programs (18%), self-funding (15%), PBS (2%) and other currently unknown mechanisms (31%).
- Overall, 461 (14.3%) of the cohort have received a therapy as a direct result of MoST molecular screening, with a median survival of 17 months compared to 11 months for those patients who did not receive a matched therapy (Fig B).
- Currently, the most commonly followed treatment recommendations as a result of MoST screening and outside of a MoST clinical trial were immunotherapies (~40%) and PARP inhibitors (~20%).

Some of the patients we have helped

Patient

Female, 68 years old

Diagnosis

Metastatic triple negative breast cancer diagnosed at age 62. The patient was

MoST screening findings and treatment recommendations:

- BRCA1 mutation > PARP inhibitor
- NF1 duplication > MEK inhibitor

Treatment decision:

Based on MoST findings, the patient began on a PARP inhibitor.

Results:

Patient experienced a marked response and scans showed that except for two lesions, all of the other metastatic lesions had completely or almost completely resolved. The patient remains on treatment.

Patient

Male, 53 years old

Diagnosis

Lung adenocarcinoma (Nov 2014); the cancer metastasised despite surgery, radiation, chemotherapy and 13 cycles of

MoST screening findings and treatment recommendations:

- MET gain of function > MET inhibitor
- MDM2 amplification
- CHEK1 duplication
- MLH1 mutation

Treatment decision:

Based on MoST findings, the patient began on a MET inhibitor.

Results:

The patient has had a complete response with his scans now clear.

"MoST screening has provided me benefit by recommending the class of drugs that would be effective against my cancer"

Real de-identified patient case studies. Patient images are hypothetical.

Patient

Female, 49 years old

Diagnosis

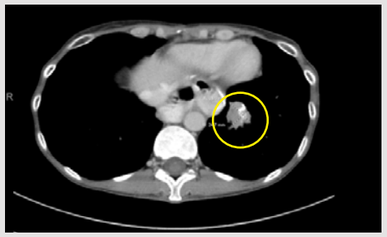
A form of invasive stomach cancer; already metastatic and displaying widespread spread into nearby lymph nodes and other organs. Family history of various cancers. She had her entire stomach removed along with resection of her spleen, distal pancreas, left adrenal gland and liver.

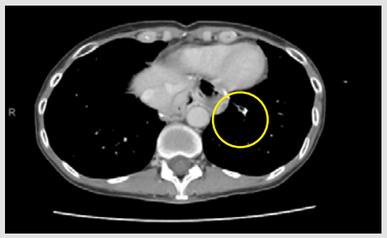
MoST screening findings and treatment recommendations:

- High TMB > Immunotherapy
- PIK3CA gain of function > PI3K inhibitor
- SMARCB1 mutation > EZH2 inhibitor
- MSH2 frame shift mutations (x2) > Immunotherapy

Treatment decision:

Based on MoST findings, she joined a MoST clinical sub study of two immunotherapies in combination.





Results:

After under a year on the sub study (Mar 2019 – Feb 2020), her treatment was stopped due to complete response to the therapy. As of Jan 2021, the patient's scans remain clear and she is continuing to show no evidence of recurrence.

"I'm doing really well and am grateful for participation in the program… I just wanted to say thank you to the MoST team for doing a great job and that they are making a real difference"

Real de-identified patient case study. Patient image is hypothetical..

Translational Oncology Laboratory (TOL)

The TOL is building on a background of expertise in molecular and biological analysis of patient samples. Analyses focus on MoST trial substudy samples with the aim of identifying biomarkers that might indicate a response to therapies.

Laboratory testing includes:

Genomics: DNA sequencing (whole genome and exome sequencing, targeted sequencing), assessment of tumour mutation burden (TMB), circulating tumour (ct) DNA and cell free (cf) DNA, T-cell and B-cell receptor repertoire and microbiome analysis.

Transcriptomics: RNA sequencing, fusion gene detection and quantitation, Nanostring™ transcript quantification (bulk and spatial), immuno-epitope profiling and single cell transcriptomics in collaboration with the Garvan-Weizmann centre for Cellular Genomics.

Protein Based Assays: ELISA, multiplex bead arrays, Western blot analysis, proteomic profiling using mass spectroscopy in collaboration with the ProCan program (CMRI).

Cell based Assays: Immunohistochemistry (IHC), Multiparametric flow cytometry, phenotyping of immune cells, activation state and proliferation and intracellular cytokine staining.

Precision medicine and companion diagnostics:

TOL is currently working up assays to assess key biomarkers that might be better at identifying and matching patients to drugs being trialled in the Molecular Screening and Therapeutics (MoST) Program.

For example, we are looking at developing companion diagnostics to determine whether amplification of the gene c-MET at the DNA level and/or high expression at the RNA level detected by next generation panel screening is correlated to high expression at the protein level. This would assist us to determine that the protein is present for drug targeting.

Fig 1. shows brain tumour samples from three glioblastoma patients, and c-MET protein expression levels. Early work suggests that patients with high MET expression at the RNA level may benefit from drugs targeting or blocking c-MET. Similar work is being carried out for the Larotrectinib trial where TRK1 and 2 expression is being assessed in suspected NTRK fusion tumours.

In-house immunohistochemistry (IHC) capability is also being expanded. We are assessing immune checkpoint blockade targets, especially PDL1, as well as tumour infiltrating lymphocytes (TILs), and will build these analyses into our future clinical trials.

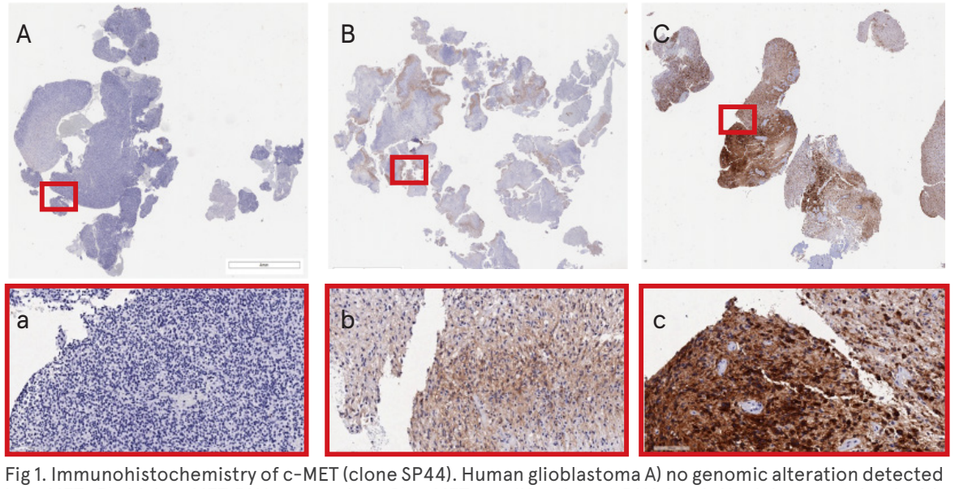


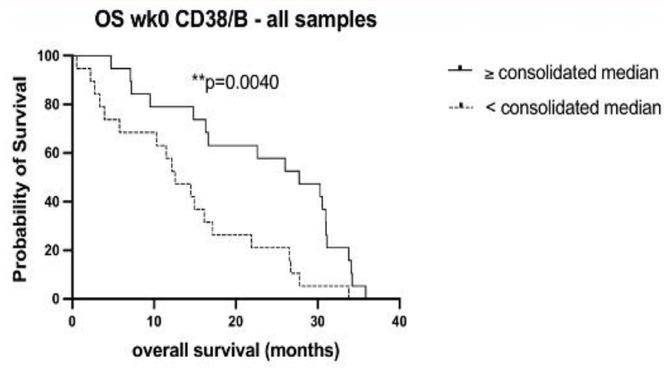
Fig 1. Immunohistochemistry of c-MET (clone SP44). Human glioblastoma A) no genomic alteration detected in c-MET, B) high c-MET RNA expression, C) c-MET amplification at DNA level. Nuclei were stained with haematoxylin. Lower case letters show corresponding regions (red box) at 20X zoom.

Correlative studies associated with our clinical trials:

We are conducting studies to assess biomarkers as indicators for good clinical response as well as for resistance. These studies are signal seeking studies to determine whether therapies that work in more common cancers may work for rare and neglected cancers. The olaparib/durvalumab MoST substudy investigated the PARP1/2 inhibitor olaparib in combination with the immune checkpoint blockade drug durvalumab (blocking PDL1) in patients with advanced solid cancers. These patients have DNA repair defects in their tumours (16 patients with defects in BRCA1/2, and 32 with defects in other DNA repair pathways). Mutations in BRCA1/2 are most commonly associated with breast cancer. We have looked at non-breast cancer subtypes with these mutations to determine if they gain clinical benefit from the drug combination. Tumours have been investigated at baseline using Nanostring TM profiling, immunohistochemistry looking at PDL1 expression, as well as CD3, CD4+ and CD8+ tumour infiltrating lymphocytes (TILs). Blood samples collected prior to treatment, after one cycle of olaparib at 4 weeks and then after both olaparib and durvaluamb at 8 weeks, are being assessed using multiparametric flow cytometry. Preliminary assessment of blood samples in patients who responded well i.e. progression free survival ≥6 months and overall survival ≥2 years, showed high numbers of B-cells expressing CD38 at all time points compared to those whose disease progressed (P=0.004) (See graph below). More double negative T-cells (P=0.04), and more conventional T-cells expressing INFγ (P=0.0473) are seen in the blood at baseline in patients who show benefit compared to those whose disease progressed. Changes are also observed in patients who respond to olaprib, and in those who respond to both drugs. These studies allow us to identify patients based on blood biomarkers that may have a better response to the combination therapy, and help us design better clinical trials.

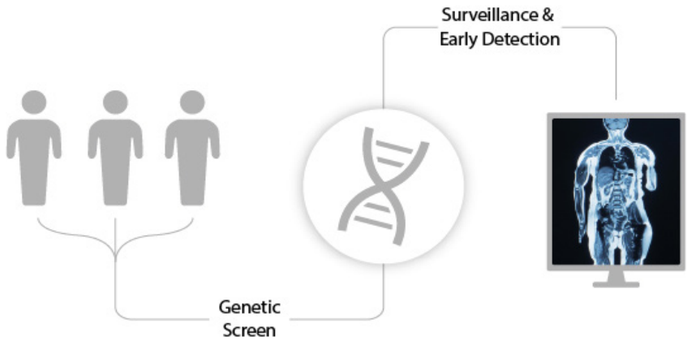
In the durvalumab/tremelilumab MoST substudy, we are investigating the response of patients with advanced cancers to dual immune checkpoint blockade. We are at the 18 month follow up point from the last patient recruited on this trial. To date, patient samples have been assessed for tumour and immune cell associated PD-L1 expression; TMB; transcriptional immune profiling in tumour using Nanostring TM; lymphocyte to neutrophil ratio in blood; cytokine expression in blood including interleukins 6 and 10 and interferon gamma at baseline and cycle 1 of dual treatment. Immune cell phenotypes and markers of activation and exhaustion in blood have been identified. Single cell transcriptomic analysis is being conducted on bloods from patients at baseline and following cycle 1 and or 2 of treatment.

Correlative studies are being undertaken for 5 other MoST substudies.



Graph showing that B-cells expressing higher levels of CD38 at baseline in blood correlates with better overall survival (OS) in patients treated with olaparib and durvalumab.

Genetic Cancer Risk in the Young (RisC) study



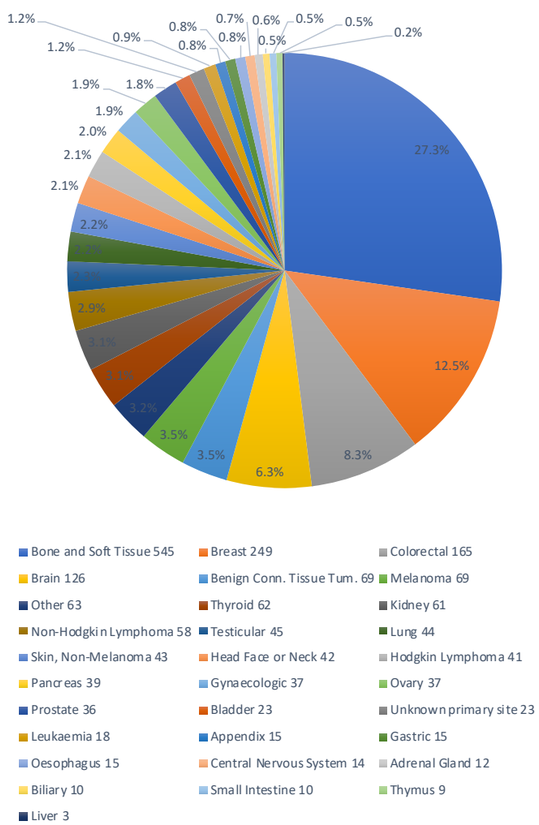
Early onset cancers represent a significant burden of cost, morbidity and mortality to the community. Evidence suggests that cancer in the young is largely driven by heritable causes and there is a higher risk of developing a second cancer as well as implications for family members.

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 information 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



The different cancer types identified in RisC patients

By the end of August 2021:

- 1522 probands* have been enrolled from around the country
- 360 family members have agreed to participate
- 1779 DNA samples have been collected
- 1278 probands have complete germline whole genome sequencing
- preliminary analysis of the first 890 whole genomes showed 51 clinically actionable pathogenic variants giving a detection rate of 5.7%
- 192 (22%) of 855 evaluable pedigrees have met criteria for germline genetic testing

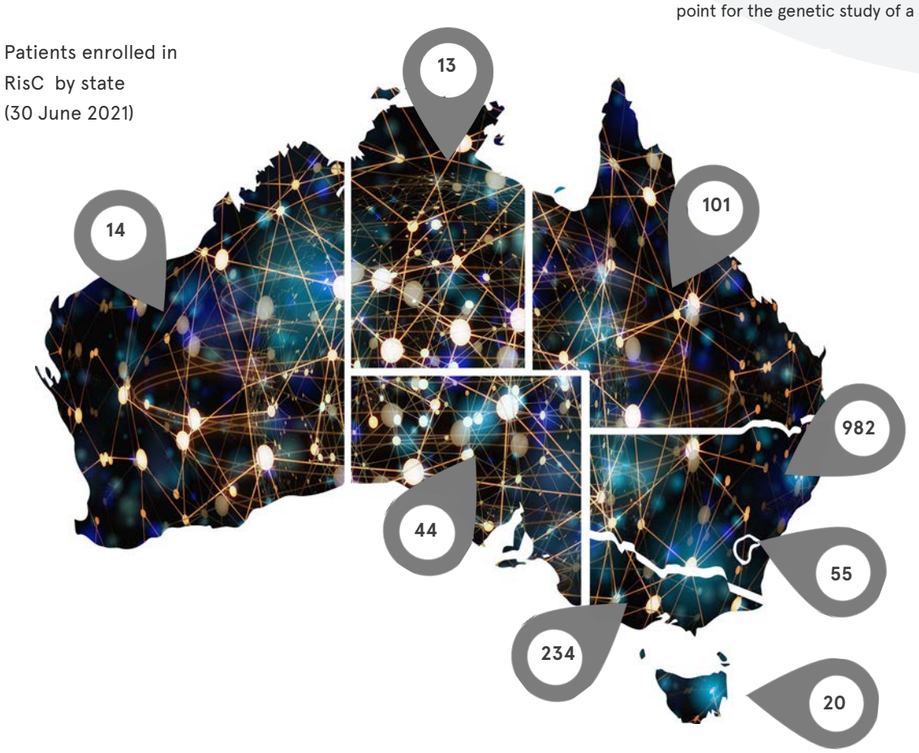
Of the 1522 cancer probands across Australia enrolled onto the RisC study, more than 20% of probands have had multiple primary cancers across a diverse range of cancer types.

Omico and the Centre for Economics Impacts of Genomic Medicine (GenIMPACT) at Macquarie University, led by Professor Deborah Schofield, are continuing to gather data (Medicare, diagnostic - routine and outcome, and cost diary data).

Economic modelling to estimate the cost of premature death due to cancer is under development. The development of the model will involve synthetic matching of RisC cohort's patient details with STINMOD (microsimulation model for tax, and welfare) and mortality data (ABS). The preliminary model is expected to be completed in 2022.

* a proband is a person serving as the starting point for the genetic study of a family

Patients enrolled in RisC by state (30 June 2021)



Surveillance in Multi-Organ Cancers (SMOC+) study

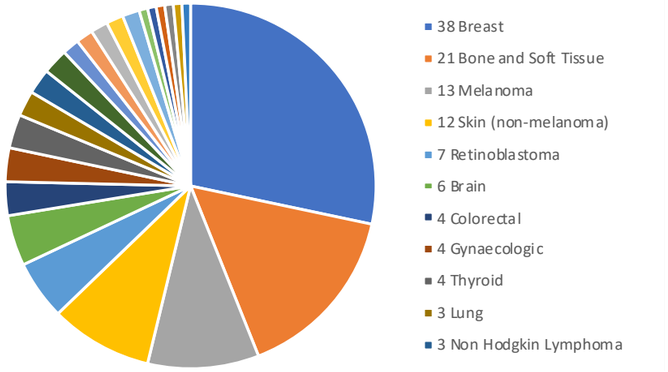
The SMOC+ Study is currently recruiting in New South Wales, Victoria and South Australia. As at 30 June 2021, 115 individuals have been consented to participate in SMOC+. Eighty-three percent of SMOC+ Study participants have TP53 mutations, and as such are classified as having Li-Fraumeni Syndrome.

Thirty two new primary cancers have been identified in 23 individuals (20%).

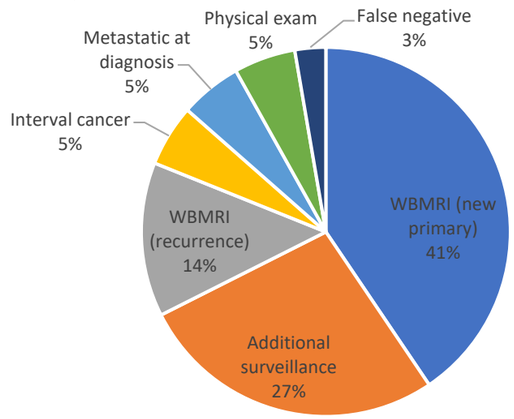
SMOC+ has addressed an unmet clinical need for surveillance in cancer-prone individuals, which is highlighted by the continued recruitment to the study.

Over 800 psychosocial questionnaires have been completed by participants in the SMOC+ Study, and statistical analysis is currently underway. An application to the Medical Services Advisory Committee for consideration of annual whole-body MRI for TP53 mutation carriers has been fast-tracked and is currently under review.

In collaboration with the Sydney Children's Hospital, the SMOC Junior Study protocol to investigate surveillance in children at high risk of developing cancer has been finalised. The study is due to open within the next few months, with multiple families interested in enrolling their children.



The range of cancer diagnosed in SMOC+ Study patients. Breast cancer and sarcomas account for 44% of all cancers diagnosed.



At least 55% of all cancers (new primary or recurrences) were detected via whole body MRIs (WBMRI).

Advocacy and support

Rare Cancers Australia (RCA)

Patient Support Program – The RCA Patient Care Team has a staff of 3.5 FTE and is currently providing support via direct contact (verbal or written) to 500 patients with either rare or less common cancers.

In the period 1 January to 30 June RCA has provided verbal or written support to over 500 patients. Of these, 85 patients have been provided information about and referred to the AGCMC Program (MoST).

Centre Visits – Prior to the current lockdown RCA had scheduled briefing visits to major Sydney Hospitals. When possible RCA has attended local and Sydney based hospitals (including St Vincent's Public and Private) but our efforts in this area have been severely restricted due to COVID

Web & Social Media presence – RCA has continued to maintain a strong social media and web presence

Digital Production – RCA has also produced a series of easily understood videos which explain complex subjects such as clinical trials, personalised medicine and the MoST study. Over the past two months RCA has commenced a series of explainer videos around the current COVID outbreak. These are being widely shared on social media and other digital platforms.

Patient Advisory Board – Continuing to function and providing constant and valuable input to RCA's work in patient support.

Transport & Accommodation – RCA has put in place processes and procedures to manage logistics for patients in need of assistance for travel and accommodation. RCA is continuing to assist patients in this area as required

Advocacy & awareness – During this six (6) month period RCA undertook a number of initiatives. In collaboration with Omico, RCA prepared a Midterm Update as a Report to Parliament. The report provided a succinct overview of the impact and importance of the Omico project to date and the opportunities in the years ahead. (Copy attached)

The report was then launched at a Parliamentary event in partnership with the Parliamentary Friends of Cancer Care and Cures. Speakers included Prof David Thomas, 2 Omico Patients and was hosted by the Hon Katie Allen MP and Senator Deb O'Neill.

> A place to learn, someone to listen, help with navigating the journey or advice

Rare Cancers Awareness Day – As part of RCA's ongoing awareness raising activity, we hosted the first Rare Cancers Awareness Day on June 26, 2021. The event was primarily a social media campaign and it reached over 2 million viewers across 4 countries including Australia, USA, New Zealand and the UK.

Government & Public Policy – Based on the work of both RCA and Omico we are jointly presenting policies to Federal and State Government that continually emphasise the need for ongoing support and funding of the Program and the increasing application of genomic science to the care of Australians living with cancer. Our work has resulted in Health Minister Greg Hunt forming a Ministerial Roundtable under the direction of Cancer Australia CEO Professor Dorothy Keefe. The roundtable will undertake the modernisation of Australia's National Cancer Plan and the research contained in the RCA Vision 20-30 report will be central to those considerations.

Richard Vines, CEO of Rare Cancers Australia was invited to speak at the Ministerial Roundtable and to address the "Zimmerman" Parliamentary Inquiry.

Mr Vines and other RCA Staff have also spoken at a series of events, both in Australia and the Asia Pac Region, on the subject of rare cancer patients and their needs including the ARCS Conference in Sydney.

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

the community.

Communications – RCA has recruited a Communications Manager and this has resulted in continuing media coverage around work of Omico and Professor Thomas. A series of articles by News Corp highlighted the need for genomic testing to be made available to all Australians living with a non-curative cancer.

Engagement Metrics 2021

RCA is continually working to engage Australians across a broad range of digital platforms, social media and traditional media. Total reach during the period 529,994.

Summary

Rare Cancers Australia is delighted to be part of the Omico Program, and we are pleased with our progress during this second difficult year of the project. We look forward to continuing our substantial support and contribution over the coming years of the project.

Rare Cancer Portal

AUSTRALIAN 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 national and international rare cancer expertise for Australian patients. The ARC Portal is embedded within and managed by BioGrid Australia - 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.

Achievements over the last 12 months

In late 2020, the ARC Portal received ethical approval allowing for a fully online consent process to help streamline the enrolment process. This was of particular importance due to reduced face-to-face patient doctor interactions in view of ongoing COVID-19 restrictions.

At the same time, the breadth of patients and specialists able to use the ARC Portal facility was expanded to include metropolitan patients. This was due to clinician and patient requests for assistance, highlighting that patients residing in metropolitan areas can face similar challenges to rural and regional patients, in accessing appropriate rare cancer expertise.

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

Promotion of ARC Portal to clinicians and experts

The ARC Portal currrently has over 130 clinicians registered as referrers. These referrers are well represented from every state and territory and include clinicians from regional and metropolitan centres. In addition, 64 medical oncologists experts in treating rare cancers (Australian and international), have provided expert input into referred cases. The ARC Portal has developed collaborations with expert tumour groups (such as the Australasian Gastro-Intestinal Trialist Group (AGITG) and Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)); clinical trial groups (New South Wales Early Phase Clinical Trials Alliance (NECTA)); and consumer organisations (Rare Cancers Australia (RCA), Neuroendocrine Cancers Australia (NECA)).

The Clinical Oncology Society of Australia (COSA) has formally endorsed the ARC Portal.

Over 700 individual patients with rare cancers registered

The ARC Portal has been referred 730 patients with rare cancers from across Australia, with referrers requesting access to sub-specialist opinions; identification of relevant guidelines or literature; molecular testing advice or interpretation; other requests; and enrolment into research programs.

Two thirds of patients had active disease, with either a new diagnosis (21.6%) or relapsed/progressing disease (46.7%), with the remainder stable (17.3%) or in remission (14.5%).

Contribution to a national rare cancer research biobank

Patients referred to the ARC Portal have consented for collection of the de-identified clinical data into the WEHI Stafford Fox Rare Cancer Program. The majority have also provided consent for researchers access to stored tumour and other samples, helping to generate an invaluable national biobank of clinically annotated rare tumour specimens.

Publications (74 to date)

2020

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2021

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Presentations - International

2020

1. May 2020 D Goldstein ASCO20 Virtual Scientific Program - Return of results after somatic tumour mutation profiling in advanced cancer: Psychological impacts (poster)
2. 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)
3. June 2020 D Thomas European Calcified Tissues Society (ECTS) Webinar Series, June (invited speaker, virtual) - Osteosarcoma
4. September 2020 D Thomas Invited speaker - Roche UTEC Precision Medicine Symposium, Peru: Establishing a national program in precision oncology: the Australian experience?
5. 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
6. October 2020 D Thomas Invited speaker - Japanese Cancer Association 2020 Annual Meeting: MTOR signaling orchestrates stress-induced mutagenesis facilitating adaptive evolution in human cancers
7. November 2020 D Thomas invited speaker - Connective Tissue Oncology Society Annual Meeting (virtual meeting) – Sarcomas as a paradigm for global collaboration
8. November 2020 D Thomas invited speaker - New Zealand Society for Oncology Personalised Healthcare Summit, (virtual meeting) - The Australian Genomic Cancer Medicine Centre: a national precision oncology platform

Presentations - National

2020

1. 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
2. February 2020 D Thomas Invited speaker – Lung Cancer Foundation Community Forum, Victoria: Personalized medicine - Advancements, access & understanding in genomics
3. February 2020 D Thomas Invited speaker – Genomic Cancer Clinical Trials Initiative Workshop, Sydney: MoST: Update on current and imminent studies of genomic profiling to guide cancer treatment.
4. 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
5. February 2020 M Kansara Invited speaker - Clare Valley Bone Conference, South Australia: Bench to beside; New Therapeutic Opportunities in Osteosarcoma.
6. February 2020 M Kansara Invited speaker - Children's Oncology Symposium, Hudson Institute, Victoria: Osteosarcoma and IL23
7. March 2020 M Ballinger Invited speaker - The Royal College of Pathologists of Australia Pathology Update (cancelled): Heritable cancer risk in the genomic era
8. 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
9. 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
10. November 2020 D Thomas invited speaker - Brisbane Cancer Conference, (virtual meeting) - A National Precision Oncology Platform
11. November 2020 P Butow oral presentation – COSA ASM (virtual meeting) - Psychological impact of comprehensive genomic profiling results to advanced cancer patients
12. November 2020 M Best oral presentation – COSA ASM (virtual meeting) - Advanced cancer patient preferences for receiving molecular profiling results
13. November 2020 N Bartley oral presentation – COSA ASM (virtual meeting) - Cancer patient experience of uncertainty while waiting for genome sequencing results
14. November 2020 S Vatter poster – COSA ASM (virtual meeting) - intention to change behaviour in patients undertaking genome sequencing

Presentations

2021

1. Thomas D. 'Omico: the Australian Genomic Cancer Medicine Program', Merck 4th International Cancer Research Symposium, January 2021, (Invited speaker, Virtual)
2. Thomas D. 'Experience sharing of MTB in guiding clinical decision-making', Roche China conference on precision treatment in gynecologic cancer, January 2021, (Invited speaker, Virtual)
3. Thomas D. 'Update from Australia - ISKS', EHE Foundation 360 Conference, January 2021, (Invited speaker, Virtual)
4. Thomas D. 'Omico: a genomic platform for biomarker-dependent drug development', George Clinical Webinar, March 2021, (Invited speaker, Virtual)
5. Thomas D. 'Leading your organisation to innovate', PricewaterhouseCoopers pearls event, Sydney, April 2021. (Invited Speaker)
6. Ballinger M. 'Li Fraumeni Syndrome' HGSA Cancer Special Interest Group Webinar April 2021 (Invited speaker)
7. Kansara M. 'Single arm, open label signal seeking, phase II trial to study the clinical activity of tildrakizumab in patients with advanced osteosarcoma and soft tissue sarcomas', European Society for Paediatric Oncology (SIOPE) annual conference, April 2021. (Invited speaker, virtual)
8. Thomas D. 'Omico: a national genomic cancer medicine program', Sydney Catalyst Research Showcase, University of Sydney, June 2021. (Keynote Speaker).
9. Thomas D. 'Issue Panel: Comprehensive Genomic Profiling (CGP): Can It Ever Bring

Enough Value for Routine Clinical Practice?', HTAi (Health Technology Assessment international) 2021, June 2021, (Invited speaker, Virtual)

10. Ballinger M. 'International Sarcoma Kindred Study' The Royal College of Pathologists of Australia Pathology Update July 2021 Sydney (Invited speaker)
11. Thomas D. 'Omico: A precision oncology platform for the 21st century', Bio Connections Australia 2021, August 2021, (Invited speaker, Virtual)
12. Thomas D. 'Epitranscriptome and Tumor Heterogeneity', Japan Cancer Association (JCA) 2021 Symposium, September 2021, (Invited speaker, Virtual).
13. Ballinger M. 'Precision Medicine for Childhood Cancer Surveillance in multi-organ cancer syndromes – the Australian experience' Kid's Cancer Alliance Symposium September 2021 (Invited speaker)

Australian Genomic Cancer Medicine Centre Limited

ABN 67 627 640 733

Financial Report

For the year ended 30 June 2021

Contents

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
Professor Susan MacLeman
Ms Tze Masters
Professor Kathryn North
Professor Robert Simes
Professor David Thomas

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 2021

	Note	2021 $	2020 $
Revenue from operations	2	15,837,360	10,705,326
Interest income		89,055	158,440
Total revenue and other income		**15,926,415**	**10,863,766**
Service provider and project expenses	3	(11,515,568)	(8,304,750)
Consulting and support services expenses	4	(784,440)	(509,502)
Employee costs		(276,747)	(198,920)
Other administrative costs		(184,178)	(177,982)
Total costs		**(12,760,933)**	**(9,191,154)**
Surplus for the Year		**3,165,482**	**1,672,612**
Other comprehensive income		**-**	**-**
Total comprehensive income for the year		**3,165,482**	**1,672,612**

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 2021

	Note	2021 $	2020 $
Assets			
Current assets			
Cash and cash equivalents	5	20,435,563	12,967,029
Receivables	6	32,100	244,976
Other assets	7	25,583	9,748
Total current assets		**20,493,246**	**13,221,753**
Non-Current assets			
Plant and equipment	8	1,775	-
Total non-current assets		**1,775**	
Total Assets		**20,495,021**	**13,221,753**
Liabilities			
Current liabilities			
Contract liability		4,598,400	2,500,000
Trade payables and accruals	9	2,108,251	130,682
Provisions	10	31,817	-
Total current liabilities		**6,738,468**	**2,630,682**
Total liabilities		**6,738,468**	**2,630,682**
Net assets		**13,756,553**	**10,591,071**
Funds			
Accumulated surplus	11	13,756,553	10,591,071
Total funds		**13,756,553**	**10,591,071**

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 2021

	Accumulated Funds $	Total Funds $
Balance at 1 July 2019	**8,918,459**	**8,918,459**
Surplus for the year	1,672,612	1,672,612
Other comprehensive income for the year	-	-
Total comprehensive income for the year	1,672,612	1,672,612
Balance at 1 July 2020	**10,591,071**	**10,591,071**
Surplus for the year	3,165,482	3,165,482
Other comprehensive income for the year	-	-
Balance at 30 June 2021	**13,756,553**	**13,756,553**

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 2021

	Note	2021 $	2020 $
Cash flows from operating activities			
Receipts from government grants		13,750,000	13,750,000
Receipts from other funding and other revenue		5,979,335	775,860
Payments to funding recipients, suppliers and employees		(12,347,193)	(10,617,625)
Interest received		89,054	148,692
Net cash flows from operating activities	12	**7,471,196**	**4,056,927**
Cash flows from investing activities			
Acquisition of plant and equipment		(2,662)	-
Net cash flows from investing activities		**(2,662)**	**-**
Net change in cash and cash equivalent		7,468,534	4,056,927
Cash and cash equivalents at beginning of year		12,967,029	8,910,102
Cash and cash equivalents at end of year	5	**20,435,563**	**12,967,029**

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 26 August 2021.

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 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 revenue when (or as) the performance obligations are satisfied

Revenue recognition from contracts is subject to assessment of the extent of specificity of performance obligations.

Income streams recognised under AASB 15 include membership fees, screening fees, collaborative data access agreements, event fees, and certain sponsorships that are enforceable and carry specific performance obligations.

Grant Funding
Grant income arising from an agreement which contains enforceable and sufficiently specific performance obligations is recognised when or as each performance obligation is satisfied. Such funds if received in advance will be deferred as contract liabilities until recognised as income.

Within certain grant agreements there may be some performance obligations where control of the good or service transfers at a point in time and others which have continuous transfer of control of the good or service over the life of the contract. Where control transfers at a point in time, revenue is recognised at this point. Where control transfers over the life of the contract, revenue is recognised based on either cost incurred or time whichever better 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)

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

Donations
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 not recognised as revenue where they cannot be reliably measured.

(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) Plant and equipment

Items of plant and equipment are stated at cost less accumulated depreciation. Depreciation is charged to the statement of comprehensive income on a straight-line basis over the estimated useful lives of each item of plant and equipment. The depreciation method and useful lives, as well as residual values, are reassessed annually. The estimated useful lives in the current and comparative period are as follows:

- Plant and equipment 2–10 years

(l) Employee benefits

Wages, salaries and annual leave
Liabilities for employee benefits for wages, salaries, and annual leave that are expected to be settled within 12 months of the reporting date, represent present obligations resulting from employees' services provided to reporting date. These are calculated at undiscounted amounts based on remuneration wage and salary rates that the Company expects to pay as at the reporting date, including related on-costs, such as workers compensation insurance. Obligations for contributions to superannuation plans are recognised as an expense in the statement of comprehensive income as incurred.

Notes to the financial statements (continued)

1. Significant accounting policies (continued)

(m) 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.

Key estimates – revenue recognition

Under AASB 15, the Company makes judgements in determining when it has satisfied the performance obligations and thereby when it is able to recognise revenue from any of its contracts where it may have sufficiently specific performance obligations. Similarly, under AASB 1058, where the consideration for the asset being received is significantly less than fair value (principally to further the Company's objectives), income is recognised as the residual of the difference between the fair value of the asset recognised and the consideration for that asset, after deducting any other related amounts. In such circumstances, the Company assesses and makes a judgement of the fair value of any consideration provided.

(n) New and revised accounting standards

There were no new or revised standards which became effective for the first time for the Company for accounting periods beginning on 1 July 2020.

(o) 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)

	2021 $	2020 $
2. Revenue from operations		
Revenue from contracts with customers – AASB 15		
Government funding	401,600	-
Funding and grants from corporate and institutional funding bodies	4,460,113	130,000
	4,861,713	130,000
Revenue recognised under AASB 1058 Income of NFP Entities		
Government funding	10,000,000	10,000,000
Funding and grants from corporate and institutional funding bodies	800,695	562,435
Donations	150,100	-
Other revenue	24,852	12,891
	10,975,647	10,575,326
Total revenue from operations	**15,837,360**	**10,705,326**
3. Service provider and projects expenses		
Amounts paid or distributed to service providers for projects	11,515,568	8,304,750
	11,515,568	**8,304,750**
4. Consulting and support services expenses		
Consulting and administration	671,142	424,919
Legal costs	41,675	20,831
Other costs	71,623	63,752
	784,440	**509,502**
5. Cash and cash equivalents		
Cash at Bank	20,435,563	12,967,029
	20,435,563	**12,967,029**
6. Receivables		
Contract asset	32,100	16,500
ATO receivable	-	228,476
	32,100	**244,976**

Notes to the financial statements (continued)

	2021 $	2020 $
7. Other assets		
Accrued interest	25,583	9,748
	25,583	**9,748**
8. Plant & equipment		
Computer equipment	2,662	-
Accumulated depreciation	(887)	-
	1,775	**-**
9. Trade payables and accruals		
Trade and other payables	414,273	164
ATO payable	205,094	-
Accruals	1,488,884	130,518
	2,108,251	**130,682**
10. Provision		
Provision for annual leave	31,817	-
	31,817	**-**
11. Accumulated funds		
Accumulated funds at the beginning of the financial year	10,591,071	8,918,459
Surplus for the year	3,165,482	1,672,612
Accumulated funds at the end of the financial year	**13,756,553**	**10,591,071**
12. Reconciliation of cash flows from operating activities		
Surplus for the year	3,165,482	1,672,612
Add: depreciation	887	-
Changes in assets and liabilities		
Change in prepayments	-	577
Change in receivables	212,876	(175,394)
Change in other assets	(15,835)	(9,748)
Change in contract liability	2,098,400	2,500,000
Change in trade and other payables	1,977,569	68,880
Change in provisions	31,817	-
Cash flows from operating activities	**7,471,196**	**4,056,927**

Notes to the financial statements (continued)

13. Contingencies

Nil.

14. 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.

15. Related party transactions

Key Management Personnel Compensation

The Company paid $316,379 to key management personnel during the year (2020: $279,600). There were no other transactions with key management personnel during the year ended 30 June 2021. Key Management Personnel include Board members, the Chief Executive Officer (CEO), the Deputy Chief Executive Officer and the Company Secretary. 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, $1,282,965 (2020: $1,204,500) 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, $2,982,500 (2020:$2,693,625) 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, $206,362 (2020: $200,000) was received from Garvan Institute of Medical Research as part of this funding.

Notes to the financial statements (continued)

15. Related party transactions (continued)

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. Robert 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, $4,439,303 (2020: $2,390,375) was paid to that entity by this Company under this agreement.

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. $1,500,000 (2020: 750,000) was paid to that entity during the year.

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 $716,250 (2020: $1,016,250) 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.

Central Adelaide Local Authority Network provides general and quaternary hospital services. Professor Michael Brown has been appointed as a representative member on the Board. A payment of $20,000 was made in the year towards research services provided by Central Adelaide Local Authority Network.

University of Melbourne Professor Ricky Johnstone is a representative member on the Board. A payment of $344,550 has been made in the current year towards research services provided by University of Melbourne.

There were no other related party transactions during the year ended 30 June 2021.

Notes to the financial statements (continued)

16. Events subsequent to balance date

There are no material events subsequent to balance date.

17. 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.

18. 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 non-government, corporate and institutional funders and donations to be used and distributed for the charitable purposes for which the Company operates.

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 Company is able to pay all of its debts as and when the debts become due and payable,

b) the financial statement satisfies the requirements of the Charitable Fundraising Act 1991 and the Charitable Fundraising Regulation 2021,

c) the contents of the financial statement are true and fair,

d) the Company has appropriate and effective internal controls.

Professor David Thomas
Chief Executive Officer

Sydney

26 August 2021

Responsible Entities' Declaration

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

1. The financial statements and notes set out on pages 4 to 16, are in accordance with the Australian Charities and Not-for-profits Commission Act 2012, including:

   a. giving a true and fair view of AGCMC's financial position as at 30 June 2021 and of its performance for the financial year ended on that date; and

   b. complying with Australian Accounting Standards – Reduced Disclosure Requirements and the Australian Charities and Not-for-profits Commission Regulation 2013.

2. 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:

Paul Jeans
Chair of the Board of Directors

Bruce Goodwin
Director

Sydney

26 August 2021

Grant Thornton

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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 2021, 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.

Grant Thornton Audit Pty Ltd
Chartered Accountants

B Narsey
Partner – Audit & Assurance

Sydney, 26 August 2021

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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 2021, 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 2021 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.

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.

Information Other than the Financial Report and Auditor's Report Thereon

Those charged with governance are responsible for the other information. The other information comprises the Declaration by the Principal Officer.

Our opinion on the financial report does not cover the other information and accordingly we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

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.

Grant Thornton Audit Pty Ltd
Chartered Accountants

B Narsey
Partner – Audit & Assurance

Sydney, 26 August 2021

Omico.

Australian Genomic Cancer Medicine

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