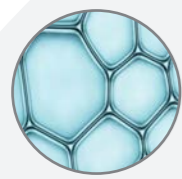


Outsmarting cancer, together

Annual Report 2022

What we achieved in 2021/2022:

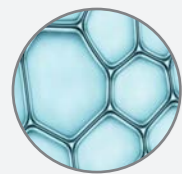
MoST patients screened



at September 2021
3759

at September 2022
5749

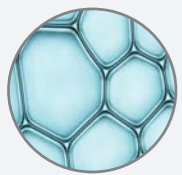
MoST patients on novel therapy studies



at September 2021
309

at September 2022
504

MoST subprograms



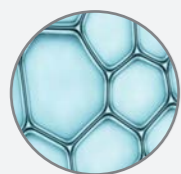
pan cancer

lung cancer

blood cancer

pancreatic cancer

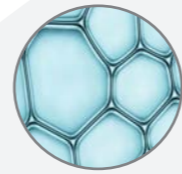
MoST recruiting sites



6 member sites

15 other sites across Australia (plus NZ)

MoST patients receiving a matched therapy after molecular screening



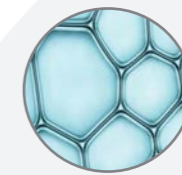
498
(12.2%)

MoST substudies

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

at September 2022
1 closed;
3 in follow-up; 17 recruiting
2 in start up; 4 referring*

Pharmaceutical industry MoST support



\$20.2m

in-kind support medicines to treat 920 patients

Philanthropic support for MoST substudies

\$4.0m

RisC participants enrolled

at September 2021
1532

at September 2022
1758

SMOC+ participants enrolled

at September 2021
117

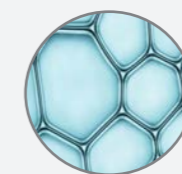
at September 2022
153

RisC probands sequenced

at September 2021
1376

at September 2022
1570

SMOC+ cancer detection



42 new primary cancers in 29 (21%) individuals

PROSPeCT - coming in 2023:



Accelerated clinical trial set-up, with access to leading centres across Australia



Rapid enrolment of eligible trial participants



More than 20,000 patients undergoing sequencing between 2023 and 2026



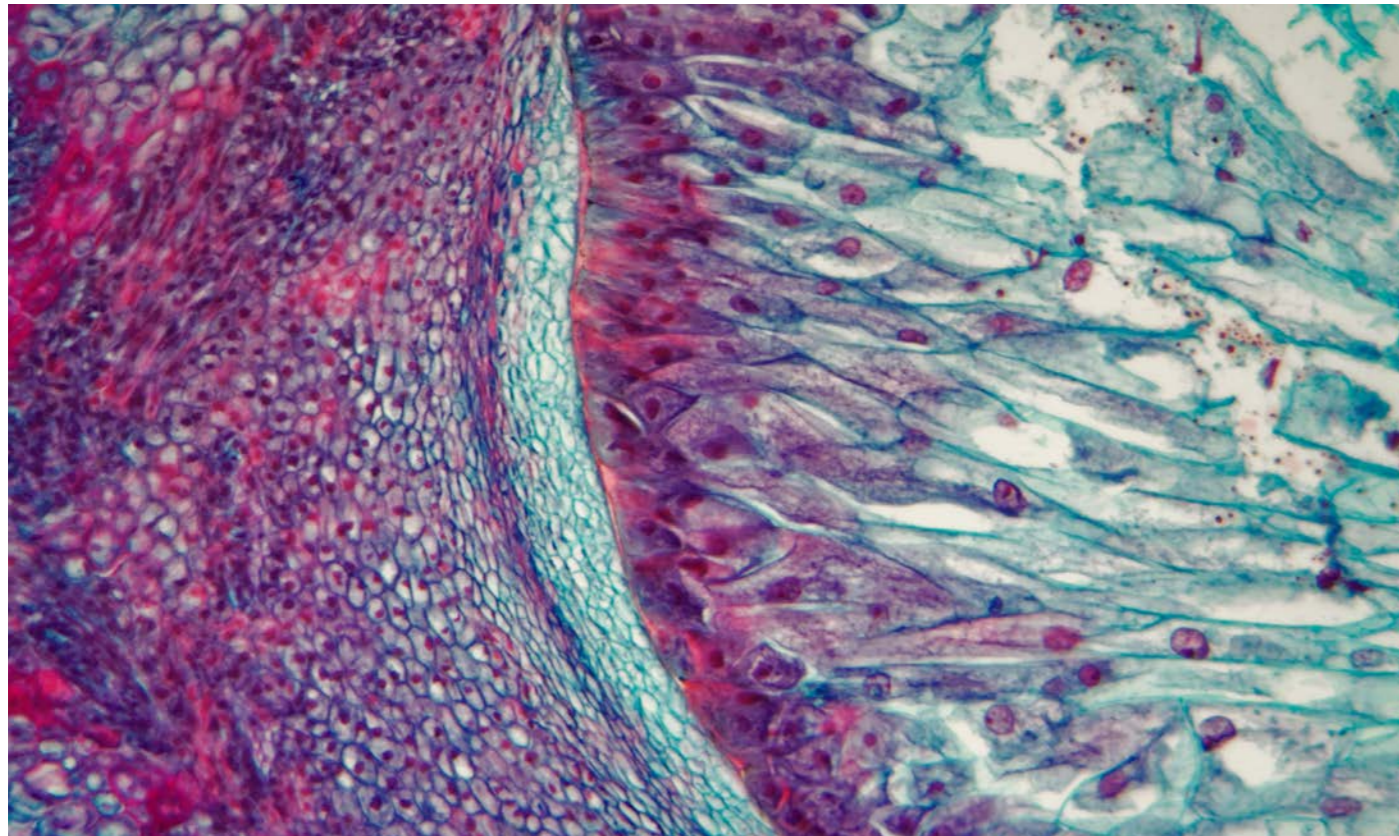
Generation of real-world datasets with international significance, helping to drive approvals in new markets

Who are we?

Omico is a not-for-profit nationwide network of research and treatment centres that facilitates, supports and promotes clinical trials in genomic cancer medicine.

Central to this is the use of precision medicine for the prevention and treatment of cancer.

By bringing together Australia's major cancer centres, leading research institutes, Federal and State governments, industry partners and patients, we are facilitating the delivery of genomic cancer medicine clinical trials to thousands of Australians suffering from advanced and incurable cancer.



What do we do?

Omico members treat more than **100,000 new cancer patients each year**, of which **more than 20,000 have rare or less common cancers**

Omico aims to:

Improve outcomes for Australians

by accelerating the use of precision oncology

and growing clinical trials

and modernising the Australian healthcare system

Molecular screening & therapeutics

Tumour profiling to evaluate biomarker-driven treatments for patients.

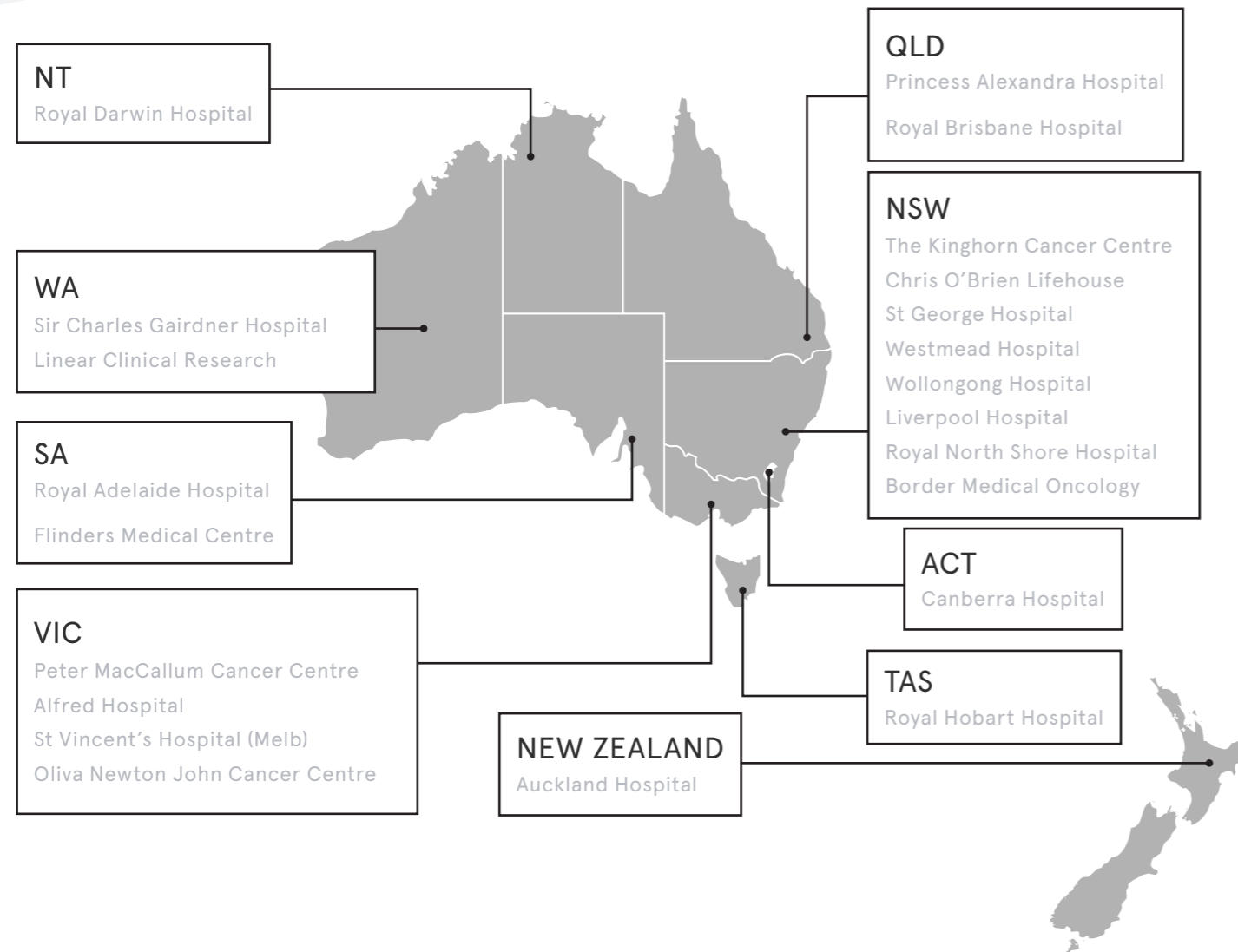
Health system reform

Leading health system reform through evidence.



Our Participating Centres

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



Our Partners



Our People

Our board



Mr Paul Jeans
Chancellor, University of
Newcastle (NSW)



Mr Richard Vines
(Deputy Chair)*



Professor David Thomas
(CEO)*



Ms Sue MacLeman



Mr Nat McGregor
(for Garvan Institute of
Medical Research)



Mr Bruce Goodwin
(for Medicines Australia)*



Professor John Simes
(for University of Sydney)



Professor Michael Brown
(Member representative)



Professor Ricky Johnstone
(Member representative)



Ms Tze Masters*



A/Professor Paul Martin
(Company Secretary)

Our leadership team



Professor David Thomas
CEO



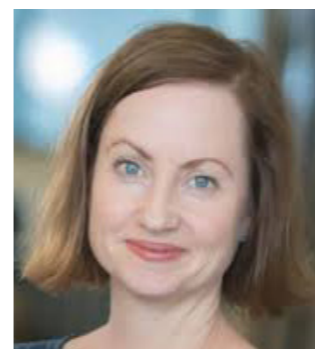
Dr Vera Terry
Deputy CEO



Mr Satish Nair
CFO (to August 2022)



Mr Waman Tamhankar
CFO (from August 2022)



Dr Mandy Ballinger
Head of Cohorts



Dr Lucille Sebastian
Program Manager

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

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,

4. make biobanked material available for further research;
5. support the collection, maintenance 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, contract research organisations and industry bodies);
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 and CEO

Dear Colleagues

2022 has seen Omico make dramatic progress across multiple fronts.

Research

The MoST program reached more than 5,900 participants by September 2022, well ahead of the original 5-year forecast for 2400 participants by this stage. Of these, more than 700 went onto biomarker-dependent clinical trials. Omico has opened 22 clinical trials over the past 4 years, and completed 4 of these to date. Our preliminary analyses of patient outcomes shows that patients who receive a therapy closely matched to biomarker identified in their tumour have a more than doubling of their expected survival. This shows the power of rationale drug development, which in turn is critically dependent on the tumour profiling that Omico provides to patients and clinicians through the MoST study. It is reasonable to say that MoST has become a valuable asset to the clinical community, with more than 400 of Australia's 600 oncologists referring onto the program to date.

The RISC and SMOC programs have also been running on track. By September 2022, RiSC has enrolled 1772 individuals who have been diagnosed with cancer before the age of 40 years. SMOC+ has enrolled more than 153 people at extreme cancer risk, offering these individuals access to whole body MRI-based screening for early cancer detection. So far, we have detected curable cancers in more than one in 5 participants. Dr Mandy Ballinger has successfully established a childhood version of SMOC (SMOC-junior), which will commence later this year for children in families with Li-Fraumeni Syndrome.

The achievements of this research are equally remarkable. Omico has enabled more than 90 peer-reviewed scientific publications to date, including the recent acceptance of a landmark paper in the prestigious journal Science. As importantly, Omico submitted to the Medical Services Advisory Committee an application to fund access through the MBS to whole body MRI for patients with Li-Fraumeni syndrome, based on our research to date. We're pleased to report that MSAC has supported funding this test to the Health Minister in September 2022. This will change forever the options available to LFS families, who have an extreme risk for

developing cancers.

We congratulate our hard-working clinical teams, led by Drs Mandy Ballinger, John Grady, Frank Lin, Subo Thavaneswaran, Christine Napier, and Lucille Sebastian, for these remarkable achievements.

These achievements have not been created in isolation, but through strong partnerships with many organisations. The George Institute, led by Professor Bruce Neal, has enabled us to diversify our clinical trials resources. The partnership with the Thoracic Oncology Group of Australia has founded the ASPIRATION subprogram of MoST, focused on 1,000 Australians with lung cancer. The partnership with the Australian Gastrointestinal Tumour Group has founded the MoST-pancreas subprogram, while partnership with the Co-operative Oncology Group in Neuro-oncology has enabled the LUMOS 2 subprogram on brain cancers. We have been able to develop a subprogram in hematologic cancers (MoST-LLy) in partnership with the Australian Leukemia and Lymphoma Group, led by Dr Steven Lane at QIMR. Professor Phyllis Butow's psycho-oncology program has generated the PIGEON project, which has focused on a deeper understanding of what genomics means to patients and clinicians. Finally, our partnership with Victorian researchers at the Austin and Repatriation Medical Centre, led by Professors Jonathan Cebon and Oliver Klein has established the MoST-Circuit program, providing immunotherapies to more than 240 patients with incurable rare cancers. Finally, we have begun to develop international partners with similar programs, such as the DRUP program led by Professor Emile Voest. This partnership has already resulted in collaborative research and a publication currently under review.

These programs represent more than \$25M of additional funding from the MRFF, CINSW and philanthropic sources that include Minderoo Foundation, the Leukemia Foundation of Australia, the Cooper Rice-Brading Foundation and others.

Our partnership with Rare Cancers Australia is fundamental to ensuring our focus always remains the thousands of Australians families affected by cancer. Their support for these families is an important part of this focus. In addition, RCA have provided guidance to Omico in its strategy development, and facilitated interactions with the Federal government in relation to future long-term funding.

Omico has continued to demonstrate strong financial governance, generating a net surplus of more than \$10M which it has reinvested into our programs of work. This surplus has come from burgeoning partnerships with industry. Industry is a critical long-term partner to Omico, as a source of funding for our activities, through bringing clinical trials to Australia, and through joint research projects. We'd like to particularly commend Roche amongst many partners making a real difference to cancer patients. Through industry partnerships, we are increasingly supporting company-sponsored trials which are further expanding the treatment options already being provided by Omico itself. We'd like to thank the inestimable Deputy CEO Dr Vera Terry and outgoing Chief Financial Officer Mr Satish Nair. We also welcome Mr Waman Tamhankar, our new Chief Financial Officer, who will take over from Satish in that role. We thank Satish for his contributions to Omico, and wish him well.

PrOSPeCT

As part of strategic long-term planning over the past 3 years, the Omico board and members have approved a major expansion of MoST, called PrOSPECT (Precision Oncology Screening Platform enabling Clinical Trials). PrOSPeCT was approved by the Federal Department of Industry Science and Resources as part of the Modern Manufacturing Initiative earlier this year, and re-confirmed by the Labour government in September 2022. PrOSPeCT is a private:public partnership led by Omico pulling together more than \$190M in funding to enable the screening of another 20,000 Australians with incurable cancers, linked to expansion of the clinical trials in Australia through foreign direct investment by the global pharmaceutical sector. This extraordinary proposal will change options for thousands of Australian cancer patients, stimulate Australian research and development, and grow the high-tech economy in Australia. It will hopefully secure long-term funding to enable Omico to continue its mission to improve outcomes for Australian cancer patients.

One major adjustment to the screening program this year was due to a change in requirements from one of the founding members of Omico, the Garvan Institute. These changes required restructuring of MoST screening in particular, and have been fully implemented by Omico.

We thank our Omico Board colleagues for their significant contribution, support and governance oversight as Omico continues its rapid development. The Board reluctantly accepted the resignation of Professor Kathy North during the year. Professor North, who heads Australian Genomics, an organisation with a major responsibility for the Australian Government's Genomics Health Futures Mission, was faced with growing responsibilities and we thank her for her significant contribution to Omico over the past three years and wish her great success in her expanded roles.

During August, the Board were informed that David Thomas will be dealing with a significant health issue over the coming months, and subsequently appointed Bruce Goodwin as Acting CEO. Bruce has been a Non-Executive Director, and Chair of the Finance, Risk and Audit committee since Omico started, and is well placed to step in during this time. David has continued to contribute strongly to Omico in the meantime, and we look forward to welcoming him back at fully capacity when the time is right for him.

Omico is most grateful to its Members for their support as it continues to grow and expand. In particular, Members unanimous approval at the Omico Extraordinary General Meeting on 22 July 2022 to progress PrOSPeCT, enabled this extraordinary opportunity.

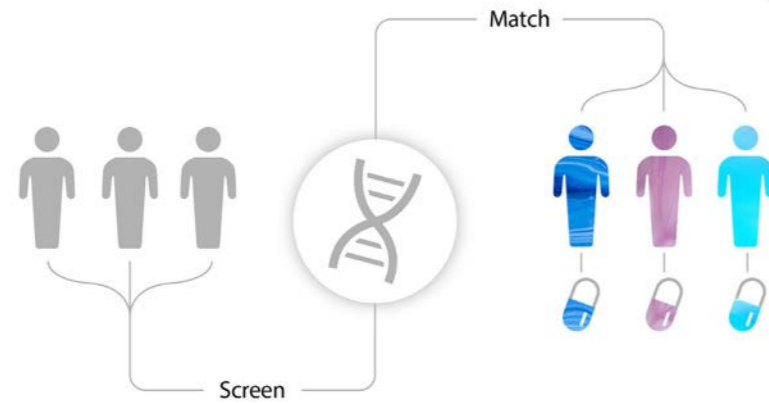
We believe Omico is poised for an exciting year in 2023. We will no doubt continue to see the rapid development of new partnerships that will enable us to reach even more Australians affected by cancer, through research that delivers direct health benefits for this country. We will also test a completely new model for sustainable future for precision oncology, one that is being watched internationally with interest.

Mr Paul Jeans (Chair of the Omico Board)

Professor David Thomas (CEO)

Research Highlights

Molecular Screening and Therapeutics Program (MoST)



The MoST Program continues to deliver molecular screening and trials matching to advanced cancer patients.

COVID-19 continues to challenge us but our partners and members of the national network remain committed to ensuring the patients under their care received access to the best treatment.

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

During 2022 we have continued to expand the pan,

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

blood, lung and pancreatic cancer groups.

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.

MoST pan cancer cohort screening update:

In total, over **5175** (including 71 in NZ) 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 76% with rare cancers, 4% less common cancers and 20% with common cancers. More than 36% of patients are currently referred from outside NSW.

MoST - New Zealand cohort:

New Zealand has joined the MoST family by launching MoST-NZ at Auckland City Hospital. This team is led by Dr Michelle Wilson and run in collaboration with Foundation Medicine, part of the healthcare company Roche. To date, **71 New Zealanders** have enrolled into the NZ MoST counterpart.

ASPIRATION lung cancer cohort:

After a delayed start due to COVID-19, **573 of 1000**

newly diagnosed metastatic, non-small cell lung cancer patients have now been enrolled onto the ASPIRATION subprogram. These patients represent an additional 1000 individuals accessing comprehensive genomic profiling (CGP) or molecular profiling for their cancer.

Leukaemia/Lymphoma (MoST-LLY) cohort update:

As the subprogram builds momentum, **22 lymphoma and 11 leukaemia** patients have enrolled into the cohort. Funding support from the Leukaemia Foundation, Tour de Cure, MRFF and philanthropic support have provided an additional **630 patients** access to molecular profiling for their blood cancer.

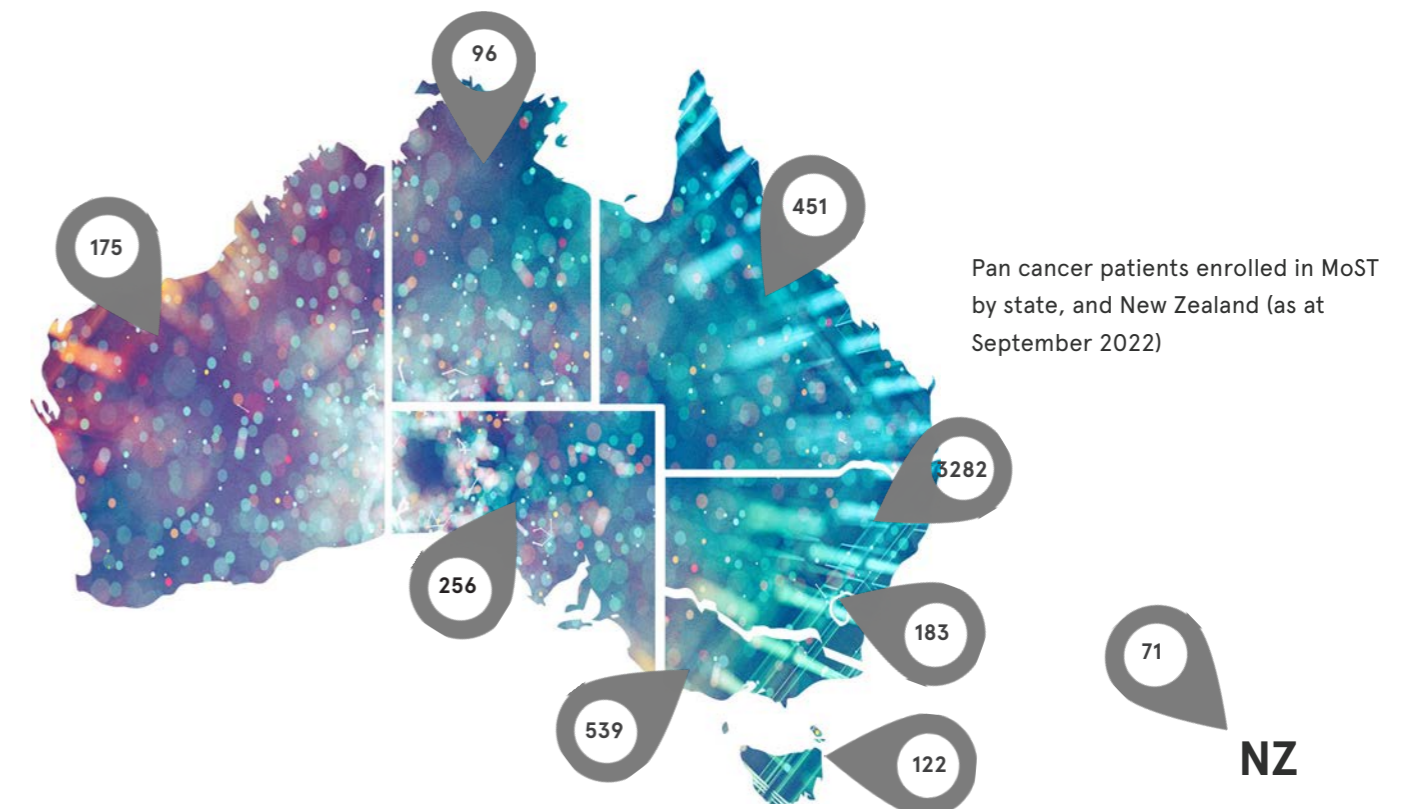
Pancreas (MoST-Pancreas) cohort update:

The pancreatic cancer cohort received funding from the Cancer Institute NSW (CINSW). It is predicted that **more than 400 patients** will be enrolled into the subprogram during the funding period.

Expanding to incorporate subprograms in blood, lung and pancreas cancer

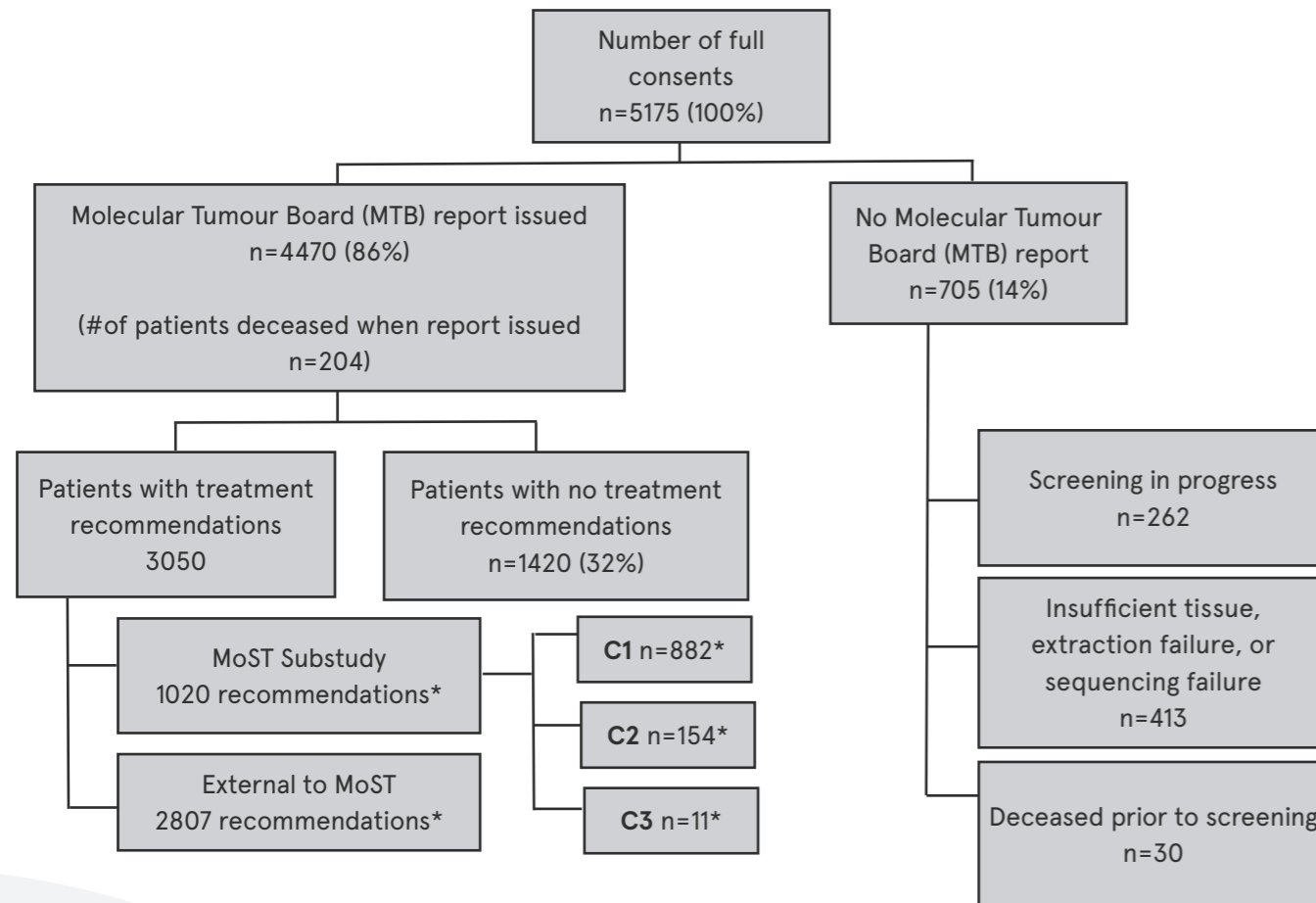
ASPIRATION and MoST-LLY patients enrolled in MoST by state

State	ASPIRATION	MoST-LLY
NSW	315	
ACT	6	
VIC	141	
TAS	29	
SA	18	13
WA	38	2
NT	7	
QLD	19	18
Total	573	33



Pan cancer patients enrolled in MoST by state, and New Zealand (as at September 2022)

About the MoST pan cancer cohort:



Of the 5175 patients enrolled, 4470 (86%) have had an MTB report issued. 2618/5175 (51%) patients are deceased, with 234/2618 (9%) deceased prior to the completion of molecular screening.

Treatment recommendations have been made to 3050 patients.

Note:

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

MoST therapeutics update

As a result of novel partnerships and our clinical trials expansion strategy, expanded treatment options are being made available to MoST screened patients.

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

Three categories of studies 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 delivered by

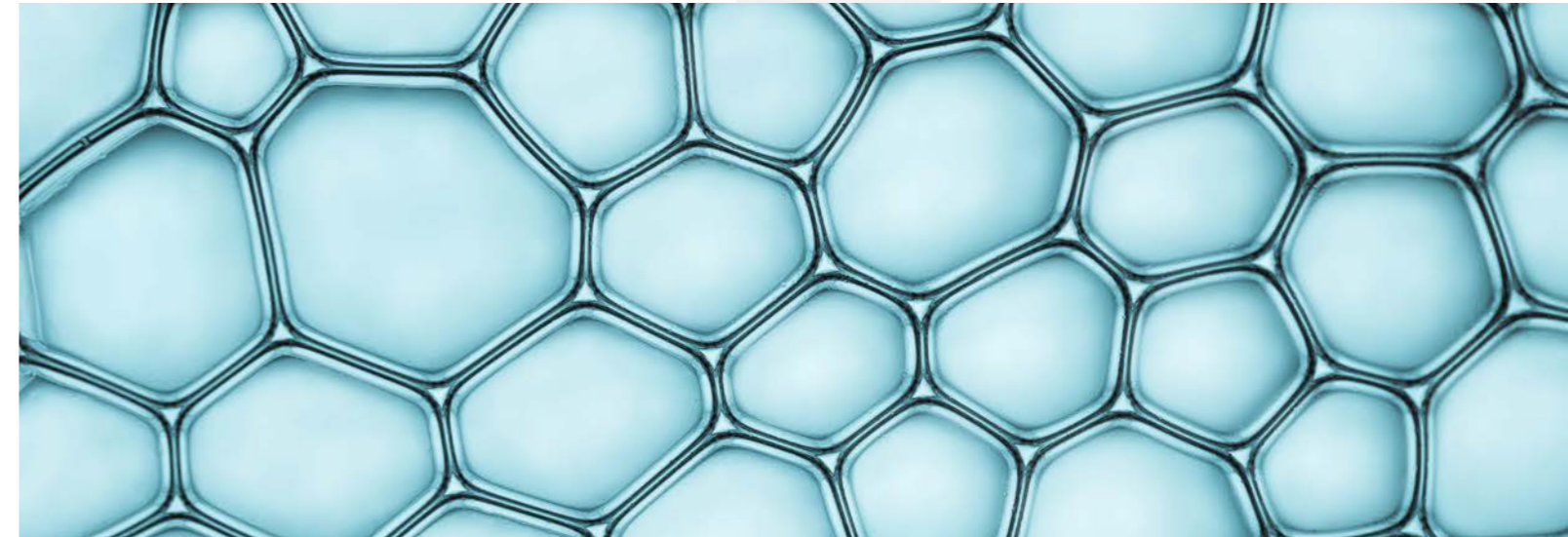
The George Institute on behalf of Omico.

MoST Company Studies (C3) - are studies sponsored by industry partners. These studies are supplementary 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 more than 1000 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	14/16
5.	Eribulin (pan cancer)	in treatment and follow up	16/16 (closed to recruitment)
6.	Larotrectinib (pan cancer)	recruiting	15/32
7.	Tremelimumab (pan cancer)	recruiting	19/24
8.	Trastuzumab emtansine (Kadcyla) (pan cancer)	in treatment and follow up	32/32 (closed to recruitment)
8+	Trastuzumab emtansine (Kadcyla) (ASPIRATION)	recruiting	10/32
9.	Tucatinib and trastuzumab (pan cancer)	recruiting	10/32
10.	Palbociclib plus avelumab (pan cancer)	recruiting	64/64 (closed to recruitment)
11.	Tildrakizumab (pan cancer)	in treatment and follow up	32/32 (closed to recruitment)
12.	Vemurafinib and cobimetinib (combined pan cancer and ASPIRATION)	recruiting	23/64 (14 pan cancer, 9 ASPIRATION)
13.	Entrectinib (combined pan cancer and ASPIRATION)	recruiting	0/16
14.	Alectinib (pan cancer and ASPIRATION)	recruiting	5/16 (4 pan cancer, 1 ASPIRATION)
15.	Acalabrutinib plus durvalumab (haematology)	recruiting	8/32
16.	Pamiparib (haematology)	recruiting	0/16
17.	Tepotinib (ASPIRATION)	recruiting	6/32
18.	Durvalumab plus chemotherapy (pan cancer)	recruiting	1/16
19.	Sotorasib (AMG510) (pan cancer)	recruiting	1/32
20.	Seribantumab (pan cancer)	recruiting	2/16
MoST Companion studies (C2)			Target number
1.	MoST CIRCUit (pan cancer)	recruiting	74/240
2.	MoST Porcupine2 (RXC004) (pancreas cancer)	recruiting	4/8
3.	SPEAR (pancreas cancer)	in start up	0/32
4.	MoST TAP (atezolizumab and tiragolumab) (pan cancer)	in development	0/96
MoST Company studies (C3)			Target number
1.	Teliso V (Abbvie)	referring	8
2.	Papillon (Janssen)	referring	7
3.	Chrysallis (Janssen)	referring	5
4.	Bayer	waiting on trials to be nominated	75
5.	Boehringer Ingelheim	waiting on trials to be nominated	75
6.	Kinnate BioPharma	referring	20
Total potential recruitment numbers			1262



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 lung cancer), has continued to undertake start-up activities and site activation visits. Five

Substudy update:

1 closed
3 in follow-up
17 recruiting
2 in start up
4 referring⁺

ASPIRATION associated therapeutic substudies and two MoST-LLy blood cancer treatment substudies are open for enrolment.

Two MoST-Pancreas (C2) substudies have been developed in collaboration with The George Institute of Global Health, and are also open to enrolment.

Patient recruitment to MoST C1 and C2 studies has seen a significant uplift - 209 patients enrolled into MoST C1 and C2 studies between September 2021 and September 2022, bringing the total to **504**. This uplift has been achieved through the opening of all C1 substudies and building on a portfolio of C2 studies.

MoST core substudies (C1): the capacity to deliver treatment through the MoST substudies increased through 2021/2022. As at September 2022:

- more than 400 oncologists across the country are referring patients to screening.
- A portfolio of more than 20 therapeutic substudies catering for patients with sequencing results. Some of these sub-studies cater for both rare cancer histotypes as well as rare molecular targets, providing broad spectrum coverage of possible results from the screening platforms.
- A new collaboration with the Cooperative trials Group for Neuro-Oncology (COGNO) (C2) will see more screening and therapeutics targeting brain cancers. 5 active molecular screening centres, with participating sites in all states and territories recruiting to the screening program.
- there is an increasing 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.

Omico has been able to achieve these goals because we have:

During 2021/2022, 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 has recruited 74 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 has recruited 4 patients.
- SPEAR - a pancreatic cancer patient trial, funded by Cancer Institute of NSW (CINSW) and sponsored by Omico in collaboration with The George Institute is open to recruitment.
- TAP - a pan cancer targeted immunotherapy trial sponsored by Omico in collaboration with The George Institute will open to recruitment in Q1 2023

MoST Company studies (C3) include:

- Teliso V - patients identified with cMET amplification or mutation
- Chrysalis - activating EGFR or cMet mutation in NSCLC
- Papillon - primary EGFR Exon 20ins activating mutation in NSCLC
- Bayer and Boehringer-Ingelheim join Omico as subscribers to bring trials to Australia
- Kinnate Pharma - BRAF and/or NRAS Mutation-positive solid tumours.

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.

Established a national network

through partnerships with industry, hospitals and academic institutions

The ability to leverage industry

with consortium members already co-investing roughly eight times the funding required to run the current and future programs

Support from a strong consortium

of biotechnology and pharmaceutical companies, contract research organisations, and investment funds

Proven capabilities

to facilitate, support and promote clinical trials in genomic cancer medicine

A well-developed plan for a private-public partnership

to expand this program with the future aim to reach all Australians with an incurable cancer

Proven clinical results

that have already screened >5,000 patients and resulted in matched treatment decisions for more than >498 patients

Established partnerships

with a broad range of other stakeholders, including State Governments and international genomic studies



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.

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 collected from 1 January 2022 to 30 August 2022:

- 2413/2585 (93%) patients had at least one successful follow up attempt
- There were 4838 attempts at follow, with 3520 completed (73%)
- Of the 2585 patients that had a follow up attempt, 575 received a matched therapy (22%)
- 730 matched therapies were received in total (** note the ASPIRATION patients are included which increases the Standard of Care (SoC)-based treatment)

Of the 730 matched therapies received:

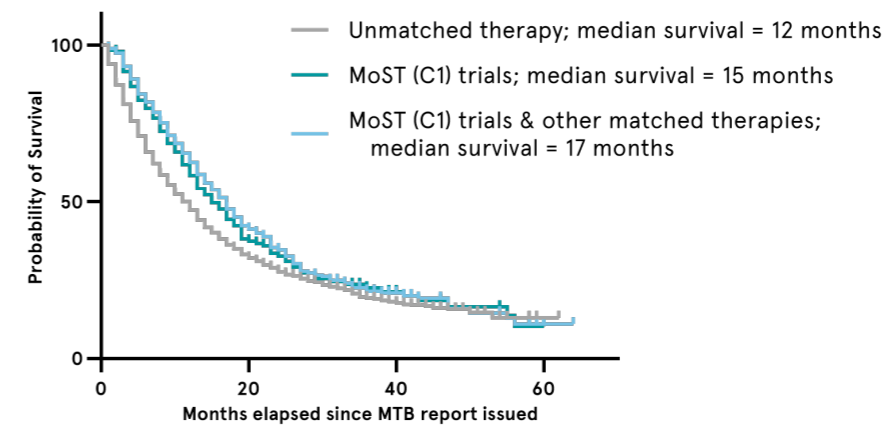
- 366/730 (50%) were based on molecular profiling

- 266/730 (36%) base on standard of care results
- 98/730 (14%) were clinical decisions prior to molecular profiling

Of the 730 matched therapies received:

- 117/730 (16%) via a clinical trial
- 193/730 (26%) via a MoST Substudy
 - C1 – 187/193 (97%)
 - C2 – 6/193 (3%)
- 68/730 (9%) via compassionate access
- 33/730 (5%) privately funded
- 157/730 (22%) via PBS
- 162/730 (22%) unknown access method

Overall survival of MoST-Pan patients



Survival curve of all MoST pan cancer patients, separated by those that received a matched therapy after MTB vs not.

Some of the patients we have helped

Patient

Female, 63 years old

Diagnosis

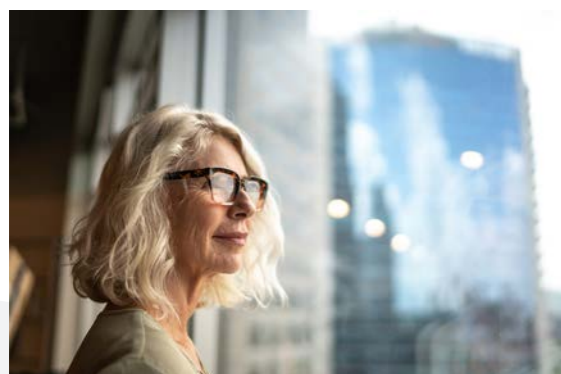
Pancreatic cancer

MoST screening findings and treatment recommendations:

- high tumour mutational burden
- mutations/amplifications in 10 genes

Treatment decision:

Based on MoST findings, the patient began on a PD-1 inhibitor.



Results:

Patient commenced immunotherapy and is still on the therapy 2½ years later with a partial disease response. In addition to identifying an actionable result, subsequent sequencing revealed an inherited cancer predisposition

Patient

Male, 43 years old

Diagnosis

Non-smoker diagnosed with metastatic non-small cell lung carcinoma at age 42

MoST screening findings and treatment recommendations:

Rare deletion in the EGFR gene not detected by standard of care testing

Treatment decision:

EGFR deletion conferred eligibility to an oral tyrosine kinase inhibitor.



Results:

The patient has been on treatment for over one year, with a partial response to disease.



Patient

Female, 35 years old

Diagnosis

Advanced medulloblastoma

MoST screening findings and treatment recommendations:

a mutation in the tumour suppressor PTCH1 gene, a member of the hedgehog signalling pathway.

Treatment decision:

Based on MoST findings, she joined a MoST clinical sub study of vismodegib.

Results:

Still on treatment 10 months later

Translational Oncology Laboratory (TOL)

Precision medicine and companion diagnostics:

Assays have been worked up to assess biomarkers that may allow better selection of patients responsive to drugs being trialled in the MoST Program. Drugs inhibiting the immune checkpoint PD-L1 have shown striking success in patients with more common cancers, e.g. melanoma and Non-Small Cell Lung Cancers that have high expression of PD-L1 at the protein level. In rarer cancers, the knowledge of PD-L1 expression is limited. Fig 1 shows a rare head and neck cancer (parotid tumour) showing a) histology with H&E staining and b) PD-L1 expression by tumour cells and c) infiltration of lymphoid cells. Investigation of PD-L1 expression, in rarer cancers, may identify other tumour types that might benefit from anti-PD-L1 treatments.

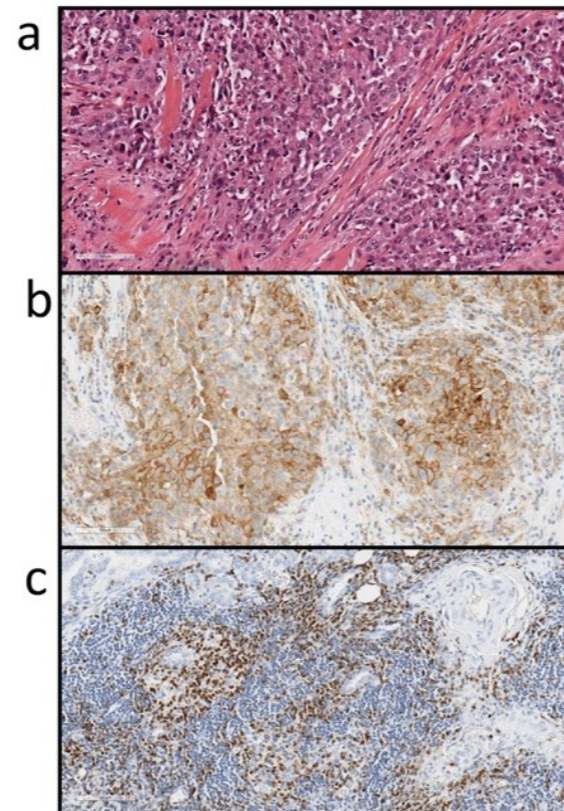


Fig 1. Parotid tumour a) histology shown by H&E staining, b) PD-L1 expression (SP263)(brown staining), and c) tumour infiltrating white blood cells, CD3+ brown staining.

Correlative studies from our clinical trials:

(1) Biomarkers for good responses and resistance

MoST 3 investigated the PARP1/2 inhibitor, olaparib in combination with immune checkpoint blockade drug, durvalumab (blocking PD-L1) (O+D) in 48 patients with advanced solid cancers. Studies investigating peripheral blood immune cells of these patients have been completed (manuscript is in review). The response of patients with advanced cancers to dual immune checkpoint blockade (durvalumab and tremelimumab) have also been investigated. Using flow cytometry, blood has been analysed for biomarkers

that could be used to predict whether patients would have a good response to D+T. In future, this may allow a more accurate triaging of good responders onto specific trials upfront. A higher proportion of circulating follicular T-helper cells CD4+ (cTfh) cells expressing PD-1+ are significantly associated with longer overall survival (OS) and progression-free survival (PFS) (Fig 2). Little is known about these cells in cancer, but in heart transplantation, higher cTfh cells in the blood are associated with host versus graft rejection, suggesting a more active immune system, which may be beneficial in cancer.

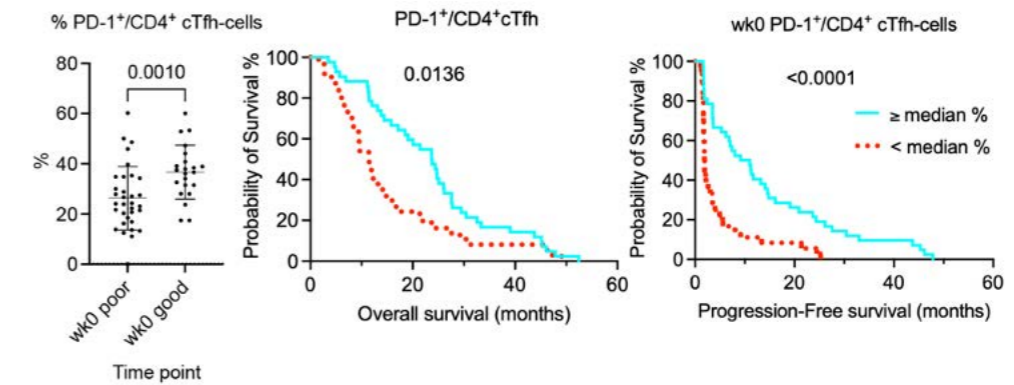


Fig 2. A higher proportion of PD-1+ CD4+ cTfh cells at baseline is significantly associated with longer overall all and progression free survival in patients treated with D+T (Mantel-Cox test)

(2) Glycosylation signatures in blood

In collaboration with InterVenn Biosciences, a pilot study investigating glycosylation signatures in blood that may correlate with outcome, was conducted. The results were presented at ASCO June 2022 (ID 11546). Samples of serum from 103 patients before D+T

treatment were assessed using mass spectroscopy for signatures of protein glycosylation Fig 3a. 529 glycopeptides were assessed, 154 significantly associated with OS (P=4.9e-08) Fig 3b. Leave out cross-validation studies, strongly distinguished patients likely vs unlikely to exhibit long-term benefit. All these studies are ongoing.

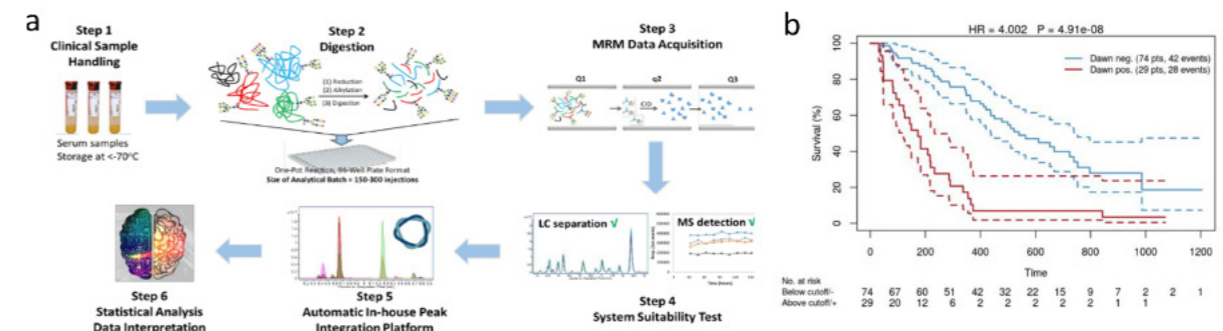


Fig 3a. Schematic of workflow for assessment of glycosylated protein signatures b. signatures are able to triage good vs poor responders in the D+T trial (see text), taken from poster ASCO 2022 ID 11546.

National Impact Across Stakeholders

Important benefits to healthcare professionals

- 400 referring oncologists engaged
- Providing access to innovative therapies at no cost to the patient
- Enabling treating clinicians to employ individualised therapies, caring for their patients in the most personal way

Meaningful benefits to patients

- Increasing the number of patients with access to screening:
 - 5,066 patients screened so far with a goal of 7,000 for the five years – more than double the original plan
- 60% of patients recommended a potential novel treatment based on their screening results
- 20% of patients placed on clinical trials and have received a matched targeted therapy
- 30% of patients on trials showing benefits such as complete responses and tumour shrinkage

Bringing opportunities to Australian Research Institutions

- Increasing access to Australian researchers and experts, with >22 member centres nation wide
- Greater research activity and more critical-knowledge-worker jobs in Australia
- Building connections between centres, and increasing collaboration between researchers and clinicians

Creating value for the Australian government

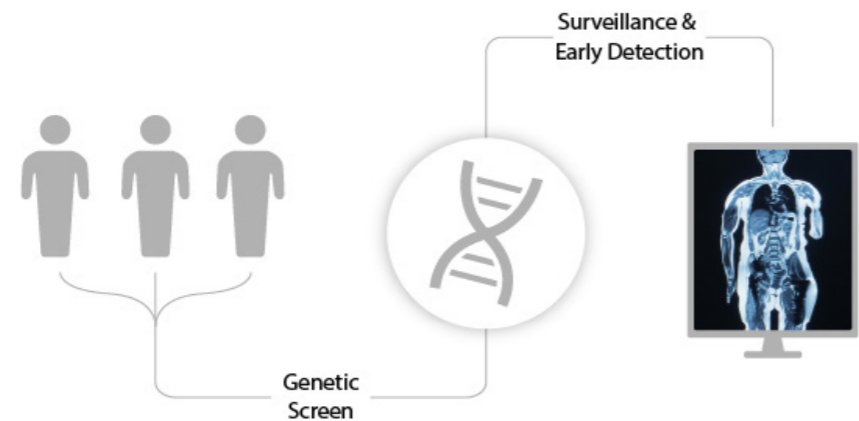
- Placing Australia among the global leaders in genomic cancer medicine
- Attracting significant foreign investment in Australia
 - \$660M in direct investment in Australian clinical trials
- Intellectual property and full supply chain in Australia, securing jobs for the future
 - Up to 650 direct and indirect jobs supported across the sector

Access and innovation opportunities to the pharmaceutical industry

- Helping industry partners find patients, initiate trials and obtain readout faster
- Lowering costs of recruitment, implementation, data collection, results and registrations



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.

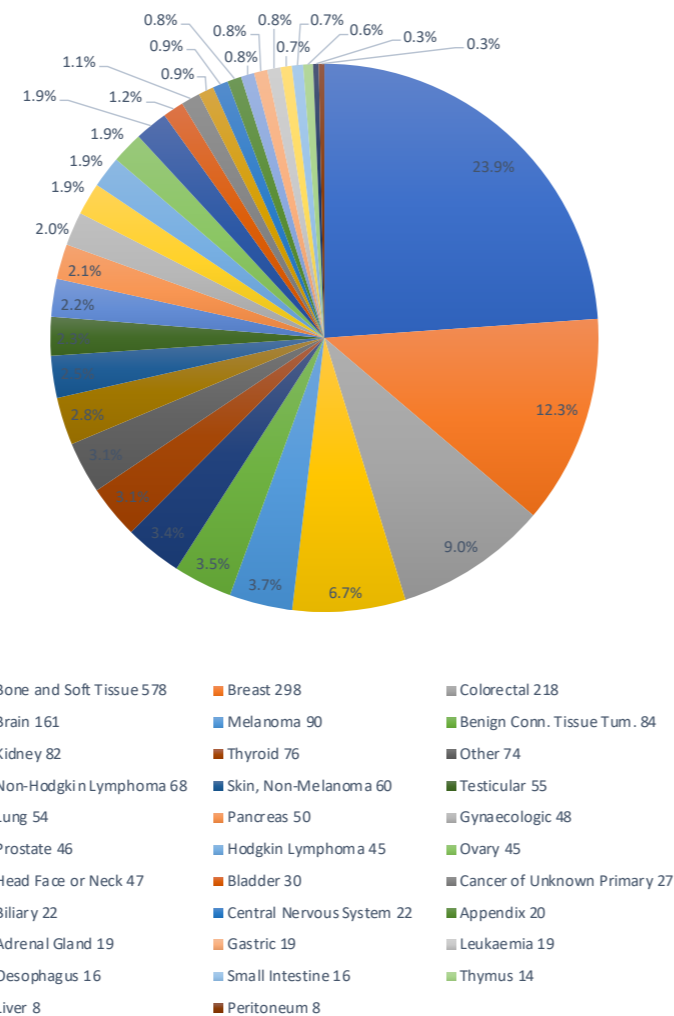
The RisC study is a clinical genomics program for early-onset cancers. RisC, and its companion the Surveillance in Multi-Organ Cancer-Prone Syndromes (SMOC+) study, have already identified cancers at an earlier, curable stage.

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

Those individuals identified as being at increased multi-organ cancer risk are eligible for participation in the companion project the Surveillance study in Multi-Organ Cancer prone syndromes (SMOC+).



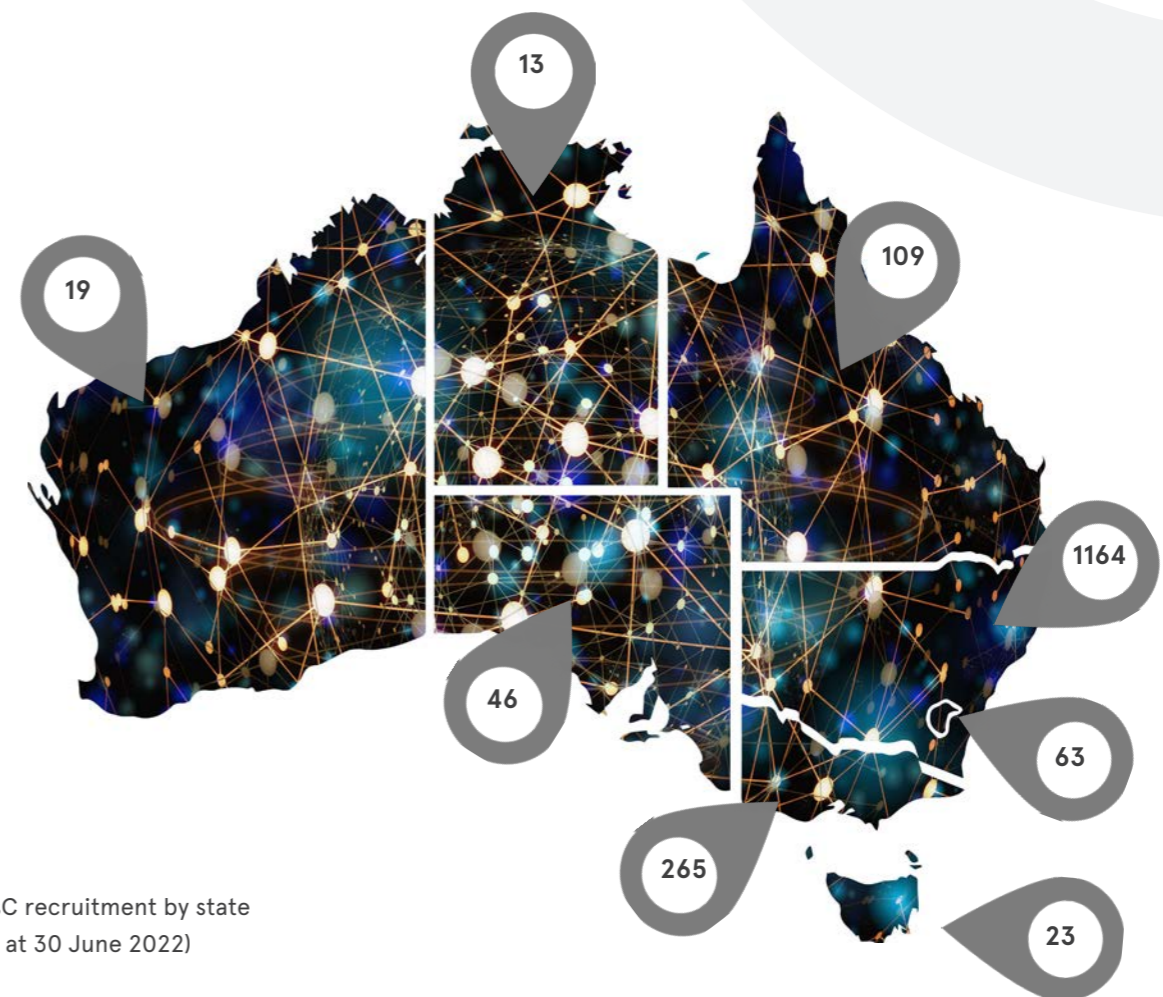
The different cancer types identified in RisC patients

By the end of June 2022:

- 1709 probands have been enrolled from around the country
- 323 family members have agreed to participate
- RisC probands are 57% female and 24% have had multiple primary cancers.
- Germline whole genome sequencing has been completed on 1423 probands
- The most common cancer types in the cohort are bone and soft tissue sarcomas, breast cancer, colorectal cancer and brain tumours. Almost 65% of the RisC cancers are classified as rare (<6/100,000 population).
- Germline results are being returned to participants and families upon request.
- A PhD candidate has had her candidature confirmed and continues her project utilising the RisC study, focussing on germline cancer predisposition in the genomic era of cancer care.

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

1709 probands have been recruited
323 family members have been recruited
1423 whole genomes sequenced



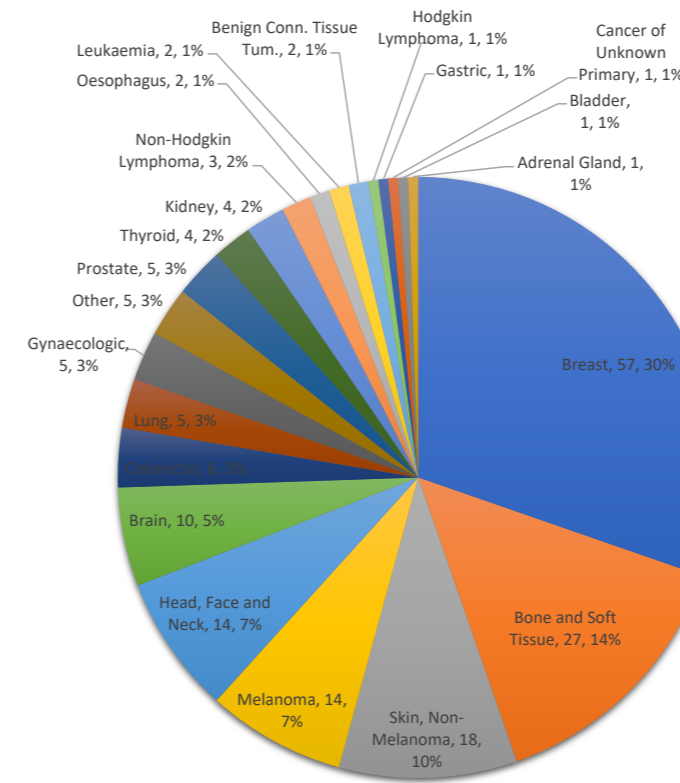
RisC recruitment by state (as at 30 June 2022)

Surveillance in Multi-Organ Cancers (SMOC+) study

- One hundred and forty-one (141) patients have been enrolled in the SMOC+ study Australia wide with 89 from Victoria, 47 from NSW and 5 from South Australia.
- Participants are on average 36 years of age (18-66y) at the time of consent with 64% female. Seventy five percent (75%) of the cohort have germline pathogenic variants in the TP53 gene (Li Fraumeni syndrome). The average age at first cancer diagnosis is 30 years. Around one third of participants have had a cancer prior to joining the study.
- Forty-two (42) new primary cancers have been detected in 29 individuals as a result of participation in the study.
- At regular intervals, the psychosocial impact of participation in surveillance is measured using validated measures. For many participants this has been completed over several years. We are currently analysing the data. Preliminary results indicate that

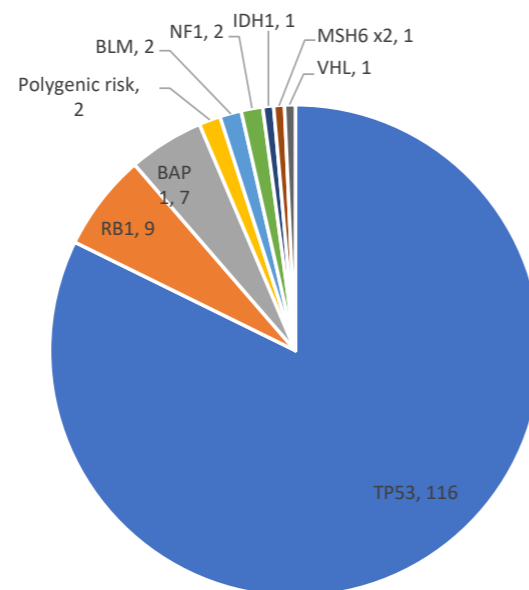
surveillance does not negatively impact a person's wellbeing. A manuscript is in preparation.

- We are in the final stages of site set up at the Sydney Children's Hospital for the SMOC Junior study which will investigate whole body MRI surveillance in children at high cancer risk.
- Based on results from the SMOC study and other international collaborations, Omico made submission to the Medial Services Advisory Committee (MSAC) for an item number to be included on the Medicare Benefits Schedule for annual whole body MRI for individuals with germline pathogenic TP53 variants (Li Fraumeni Syndrome). After completing the various stages of assessment, the MSAC has supported funding this test to the Health minister in September 2022.

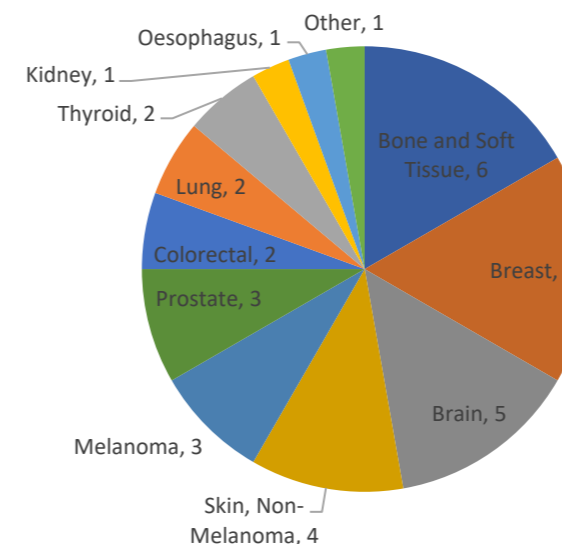


The range of cancer diagnosed in SMOC+ Study patients. Cancers of the breast and bone and soft tissue account for 45% of all cancers diagnosed, with just over 40% of cancers diagnosed being rare.

(Common >12/100,000; less common 6-12/100,000; rare <6/100,000 population per year)



Over 80% of SMOC+ Study patients have Li-Fraumeni Syndrome (TP53 mutations).



SMOC+ Study surveillance led to 42 cancer diagnoses in 29 patients (15 females, 14 males). Just over half (55%) of these new primary cancers were detected via whole body MRI (WBMRI).

A World Beyond Cancer

2016:

NSW established a state-based precision medicine initiative in Garvan's Genomic Cancer Medicine Program

- \$3.5M in funding for its Molecular Screening and Therapeutics study (MoST)
- Access to genomic screening for 1,000 NSW patients
- 3 clinical trials covering 192 participants.

2019:

NSW is the national leader in precision oncology

- GCMP obtained \$50M from the MRFF to establish Omico
- A further \$12.5M from NSW, Omico's MoST now covers 21 centres across all states and territories and has recently opened in Auckland.

Omico has impacted clinical trials, medical research and had health impact.

- 22 clinical trials in development or underway, covering almost 1,000 patients
- >450 participants with advanced cancers have received targeted therapies
- >80 peer-reviewed publications
- Omico has attracted competitive grants totalling more than \$15M to researchers within NSW.

Omico has created jobs and economic growth

- >53 direct full-time and high-value jobs have been created to date

2022:

Omico led a public:private partnership

- >20 private and public sector entities involved
- Reaching more than 20,000 Australians with advanced cancer
- Leveraging more than \$180M of federal and private sector funding
- Grew the largest precision cancer medicine network ever created in his country: PrOSPeCT.



coming in 2023

PrOSPeCT – coming in 2023

- an Australian Precision Oncology Screening Platform enabling Industry-sponsored Clinical Trials

PrOSPeCT is a public:private partnership that will grow Australia as a regional hub for cancer drug development, systematically integrating functions from fundamental research to market access. PrOSPeCT will:

- enable 20,000 Australians to access genomic screening;
- attract global investment in Australian clinical trials and build national trials capacity;
- promote collaboration and integration across the value chain;
- produce and commercialise a real-world digital asset of international significance.

The program will create up to 650 direct and indirect jobs, create a vibrant ecosystem for commercialisation of Australian medical research and grow smart businesses, and inject more than \$660M into the economy.

Leveraging more than \$120M in private investment:

- Four key stakeholders: Omico, Children's Cancer Institute (CCI), The National Computational Infrastructure (NCI), and Roche Australia; will oversee the establishment and completion of PrOSPeCT. Critically, three of the key stakeholders (Omico, NCI, CCI) are funded by Commonwealth research investment, and their participation in PrOSPeCT realises the commercialisation of Australian medical research. The key stakeholders and affiliated partners will undertake 4 major areas of work: trials matching, establishing a real-world data asset and its business model, building national trials capacity, and marketing and business development.
- Trials matching: PrOSPeCT will provide genomic screening through national adult and paediatric oncology networks. This will entail significant expansion of the current Omico infrastructure, and adaptation of the trials matching algorithms for industry partner trials. Through a remote consent model, linked

to the Australian Teletrials Program, PrOSPeCT will extend its services to rural, regional and remote Australia. PrOSPeCT will support both public and private pathology service providers to deliver the genomic screening required, and will harness the NCI for secure data storage. The marketing and business development team will work closely with industry partners in Australia, the US, Europe, and the Asia-Pacific region to bring more biomarker-dependent drug trials into the adult and paediatric networks.

- Real-world data (RWD): PrOSPeCT will collect clinical, pathologic, treatment and outcomes data on all patients recruited to **CaSP (Cancer Screening Program)**. This core dataset will be enhanced through data linkage made possible through partnership with Quantum Health, Australia's leading data analytics company. Quantum and NCI will work closely to develop analytic capacity required for commercialisation of the RWD. By the end of Year 3 of PrOSPeCT, the RWD will comprise more than 20,000 individuals. The commercialisation of the RWD will be supported through business models developed in partnership with Quantum Health.

- System trials capacity and competitiveness: PrOSPeCT will function as a co-ordinating and enabling platform for increasing collaboration between businesses that operate in the clinical trials ecosystem, ranging from contract research and maintenance organisations, workforce training businesses, small and medium-sized biotech, community and philanthropic groups, health care providers and experts, and Australia's medical research and university sector. The specific activities in this area are outlined in the project plan.

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) 800 patients with either rare or less common cancers.

In the period 1 January to 30 June 2022 RCA has provided verbal or written support to over 153 new patients. Of these, 55 patients have been provided information about and referred to the OMICO Program (MoST).

ARC Portal – RCA has initiated a joint project with Professor Clare Scott to ensure maximum patient and clinician awareness of the ARC Portal, an initiative of the Omico Project. RCA has referred 26 patients to the ARC portal in the 6 month period.

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. As part of our awareness program RCA maintained an information kiosk at Cancer Nurses Society Conference in Brisbane.

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

Digital Production – RCA has continued to produce videos and podcasts that provide information to patients and carers in an easily digested form on a range of topics including precision oncology and COVID-19 Vaccinations and Treatment.

Patient Advisory Board – Continues to function and providing constant and valuable input to RCA's work in patient support. The Advisory Board was of high value in shaping the report we released late in 2021 entitled The Rights and Roles of Australian Cancer Patients.

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 worked with OMICO to improve awareness around the opportunities for expansion of the Screening Program and the consequent benefits to both patients and the broader cancer community. RCA provided briefings to Federal Cabinet Ministers (including the Treasurer) on the health, social and economic benefits of the expanded program that was subsequently funded through the Department of Industry.

Rare Cancers Awareness Day – As part of RCA's

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

ongoing awareness raising activity, we held the second Rare Cancers Awareness Day on June 26, 2022. The event was primarily a social media campaign and it reached over 4 million viewers with 25 patient organisations, 20 corporate organisations and 50 patient advocates joining in spreading awareness for rare cancers. RCA has since been planning a bigger event to be held in 2023.

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. In the past six (6) months we have provided briefings to the Health Minister, the Treasurer and the Speaker along with multiple back benchers from all parties.

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 APEC Forum virtually.

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 and provide review and feedback on the portal content.

Communications – RCA continues to operate an active communications strategy and RCA spokespersons have appeared on all major TV Networks and have been referenced in both mainstream media and some niche publications.

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.

The screenshot shows the top navigation bar of the Rare Cancers Australia website. It includes a search icon, a 'LOGIN' button, and two prominent buttons: 'DONATE TO A PATIENT' (green) and 'DONATE' (pink). Below the navigation bar is a video player showing two women in a professional setting. The video player has a play button and navigation arrows. At the bottom of the screenshot is a dark blue banner with the text 'Cancer Support Your Way' and 'We are specialists in the experience of cancer.' Below this banner is a green button labeled 'HOW WE CAN HELP'.

Rare Cancer Portal

The ARC Portal website has been designed to help clinicians and patients learn about rare cancers and rare cancer research – as well as the ARC Portal’s online referral service. Clinicians (and their approved delegates) can register patients with rare cancers to:

- obtain streamlined access to rare cancer management guidelines;
- advice from a panel of Australian and International rare cancer specialists;
- guidance on molecular testing or interpretation of results; and
- help in identifying appropriate clinical trials.

The ARC Portal allows patients to consent for use of their clinical data, and, if they wish, biospecimens, for research.

Promotion of ARC Portal to clinicians and experts

The ARC Portal currently has over 162 clinicians registered as referrers. These referrers are well represented from every state and territory and include clinicians from regional and metropolitan centres. In addition, over 50 medical oncologists, from Australia and internationally, who are considered to be experts in treating rare cancers, have provided expert input, as required, into referred cases.

Over 1000 individual patients with rare cancers registered

The ARC Portal has been referred 1143 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. Over two thirds of patients had active disease, with either a new diagnosis (24.5%) or relapsed/progressing disease (48.2%), with the remainder stable (16.4%) or in remission (10.9%).

Contribution to a national rare cancer research



biobank and amplifying active research programs

Patients referred to the ARC Portal have consented for collection of de-identified clinical data into the WEHI Stafford Fox Rare Cancer Program. The majority have also provided consent to permit access to stored tumour specimens (83.4%) or other biospecimens (83%), such as blood or hair samples, helping to generate an invaluable national biobank of clinically annotated rare tumour specimens. Accrual has been accelerated into active rare cancer research projects, including 244 samples which have been referred for Whole Genome Sequencing or Whole Exome Sequencing (depending on fresh vs FFPE tissue or tumor purity available), with highly actionable findings identified in half (45/99) of the whole genome sequencing reports analysed to date. Tumor types studied include uterine leiomyosarcoma (uLMS, incidence 0.5 per 100,000, 67 cases enrolled, Dall et al, manuscript including genomics and PDX outcomes for PARPi therapy, nearing submission; granulosa cell tumours (incidence 0.1 per 100,000, collaboration with Prof Peter Fuller, 27 cases enrolled, 11 cases with WGS completed); adrenal tumours (incidence 0.4 per 100,000) and epithelioid haemangioendotheliomas (incidence 0.1 per 100,000; 9 cases, Ali et al, manuscript, including genomics, nearing submission). These types of projects would be challenging or infeasible to undertake with existing traditional accrual strategies that lack a national approach. We are able to facilitate multiple projects of this kind through the ARC Portal mechanism and involve a wide range of collaborators.

Facilitating rare cancer multi-disciplinary care for rural/regional patients

The ARC Portal is working with the REVITILISE network (Regional Victorian Regional Trials Alliance, Linkages, Special Populations, Equity; MRFF supported October 2020) to provide the online infrastructure which will enable a new regional Victorian multidisciplinary meeting for rare urological tumours. This targeted program will allow patients in rural and regional

Victoria with rare or complex cancers access to the same sub-specialist experts as patients able to attend specialist cancer centres. This program will act as a potential pilot program for other remote regions and rare tumour types. Importantly, this will up skill regional cancer specialists who otherwise might not have the opportunity to dial into the specialist cancer centre MDMs.

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

Integration of referrer and patient impact surveying tools into the ARC Portal platform

In 2022 Q2 the ARC Portal platform launched the version 1.4 update. A key feature of this update is the integration of surveys assessing (i.) Referrer Satisfaction and (ii.) Patient Long Term Follow-up and Portal Impact. Pilot surveys have been presented as oral abstracts at the November 2021 COSA annual scientific meeting. The update includes integration of these surveys, streamlining future data collection with associated longitudinal patient data, particularly valuable for assessing rare cancer natural history and treatment outcomes. These data will also assist us to ensure that we adapt our service as needed to provide the maximal benefit for patients and referrers.

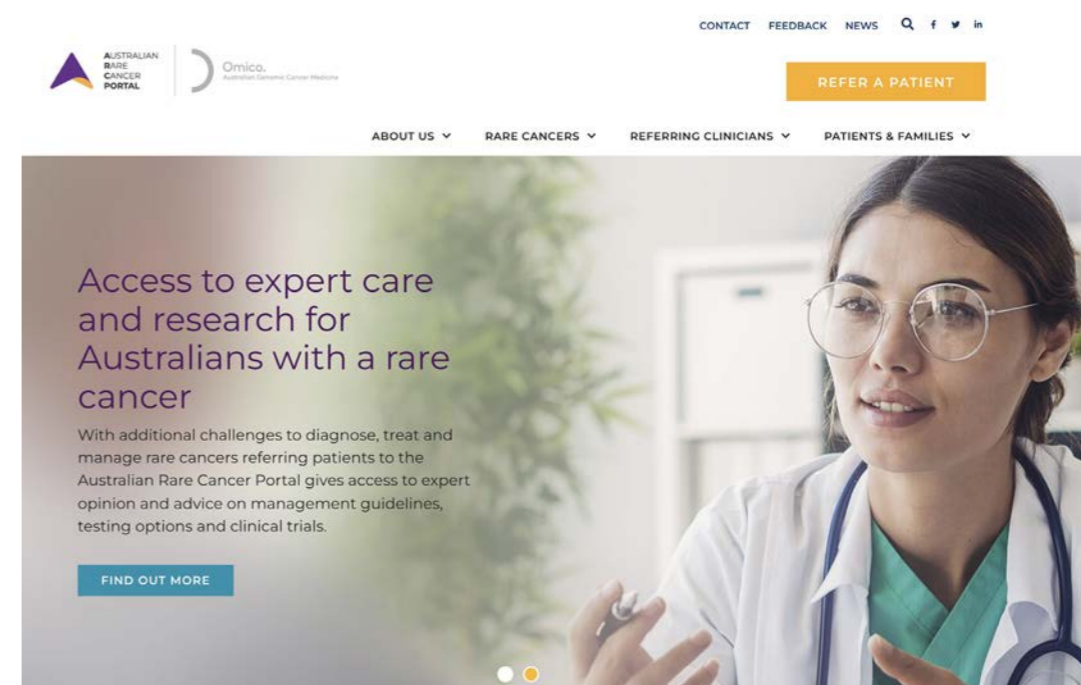
Other attainments:

Triaging and assisting patients – 2 fellows engaged; Established presence in VIC, NSW and TAS.

Reviewing year 3 activity – Survey of patient impact presented in Nov 2021 (COSA ASM). ARC Portal impacted management in 42% of referrals; of these, 39% resulted in a referral to MoST. Referrers found reports informative and relevant in 90%. Patient perspective will not be assessed as communications are directed through referrers.

Data integration, data management and reporting for Portal by BioGrid – Integration and updating of IT-infrastructure and databases to improve flow between rare cancer programs. Platform updated in June 2022 with usability improvements and integration of report outcomes, referrer usability and patient impact surveys.

Review diagnoses, molecular data, telehealth utility, impact on diagnosis, management – Integration of automated survey of referrers and longitudinal patient impact into the ARC Portal digital platform will allow ongoing collection of these data. Telehealth provision within the ARC Portal platform is no longer planned as telehealth is now provided as standard by health providers.



Research outputs

Publications (99 to date)

2021

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3. Bartley N, Davies G, Butow P, Napier CE, Schlub T, Ballinger ML, Thomas DM, Juraskova I, Meiser B, Best MC. Fear of cancer recurrence in patients undergoing germline genome sequencing. *Support Care Cancer*. 2021 May 25. doi: 10.1007/s00520-021-06311-9. Epub ahead of print. PMID: 34036439.
4. Butow P, Davies G, Napier CE, Bartley N, Ballinger ML, Biesecker B, Juraskova I, Meiser B, Schlub T, Thomas DM, Goldstein D, Best MC; Members of the PiGeOn Project. Value of whole-genome sequencing to Australian cancer patients and their first-degree relatives participating in a genomic sequencing study. *J Genet Couns*. 2021 Jul 3. doi: 10.1002/jgc4.1455. Epub ahead of print. PMID: 34218500.
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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)

2022

1. Lin FPY, Thavaneswaran S, Grady JP, Napier CE, Kansara M, et al., Molecular therapy selection in treatment-refractory advanced cancers: A retrospective cohort study determining the utility of TOPOGRAPH knowledge base. *Journal of Clinical Oncology* 40 (16_suppl), 3073-3073
2. Serie D, Pickering C, Rice R, Wong M, Huang H, Kansara M, Thomas DM, Lindpaintner K. Serum glycoproteomic signatures predict overall survival in bone and soft tissue sarcoma patients treated with immune checkpoint inhibitor therapy. *Journal of Clinical Oncology* 40 (16_suppl), 11546-11546
3. Invited speaker & Session Chair - Mandy Ballinger June 2022, 2nd International Congress of Asian Oncology Society, Seoul, Korea. Session Title: Cancer predisposition syndrome - Cancer screening recommendations for individuals with Li-Fraumeni syndrome
4. A Yuile, L Satgunaseelan, KL Alexander, S Thavaneswaran, M Krasovitsky, ME Buckland, M Lee, G Wei, M Kastelan, M Wong, I Wilson, A Beyly, W Varikat, H-W Sim, B Kong, Z Lwin, C Turner, M Back, S Miller, A Lee and H Wheeler. Clinical impact of CDKN2A/B deletions in IDH mutant

astrocytomas. Society of Neuro-Oncology 2022 Annual Meeting (International conference).

5. S Thavaneswaran USYD GMED5004 Cancer Genomics course - Lecture titled 'Treating Adult Cancers in the era of precision genomics'.
6. S Thavaneswaran YOGA workshop invited Talk titled 'Precision Medicine in Oncology, Introduction to Tumour Boards' pre-recorded for MOGA ASM August 2022.
7. David M. Thomas. A population-based, whole genome sequencing approach to mapping the genetic basis of mesenchymal malignancies [abstract]. In: Proceedings of the AACR Special Conference: Sarcomas; 2022 May 9-12; Montreal, QC, Canada. Philadelphia (PA): AACR; *Clin Cancer Res* 2022;28(18_Suppl):Abstract nr IA030.

Finances

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Australian Genomic Cancer Medicine Centre Limited
30 June 2022

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Contents

Corporate Information Statement	3
Statement of profit or loss and other comprehensive income	4
Statement of financial position	5
Statement of changes in funds	6
Statement of cash flows	7
Notes to the financial statements	8
Declaration by the Principal Officer	17
Responsible Entities' Declaration	18
Auditor's Independence Declaration	19
Independent Audit Report	20

Australian Genomic Cancer Medicine Centre Limited

ABN 67 627 640 733

Financial Report

For the year ended 30 June 2022

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

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
Mr Nathan McGregor
Mr Bruce Goodwin
Professor Ricky Johnstone
Ms Susan MacLeman
Ms Tze Masters
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

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Statement of profit or loss and other comprehensive income

For the year ended 30 June 2022

	Note	2022 \$	2021 \$
Revenue from operations	2	16,392,090	15,837,360
Interest income		86,368	89,055
Total revenue and other income		16,478,458	15,926,415
Service provider and project expenses	3	(12,584,110)	(11,515,568)
Consulting and support services expenses	4	(654,742)	(784,440)
Employee costs		(243,788)	(276,747)
Research materials		(1,001,437)	(47,800)
Other administrative costs		(229,915)	(136,378)
Total costs		(14,713,992)	(12,760,933)
Surplus for the Year		1,764,466	3,165,482
Other comprehensive income		-	-
Total comprehensive income for the year		1,764,466	3,165,482

The above statement of profit or loss and other comprehensive income should be read in conjunction with the accompanying notes.

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Statement of financial position

As at 30 June 2022

	Note	2022 \$	2021 \$
Assets			
Current assets			
Cash and cash equivalents	5	20,349,099	20,435,563
Trade and other receivables	6	406,233	32,100
Other assets	7	35,315	25,583
Total current assets		20,790,647	20,493,246
Non-Current assets			
Property, plant and equipment	8	887	1,775
Total non-current assets		887	1,775
Total Assets		20,791,534	20,495,021
Liabilities			
Current liabilities			
Contract liability	9	3,435,507	4,598,400
Trade and other payables	10	1,777,317	2,108,251
Provisions	11	57,691	31,817
Total current liabilities		5,270,515	6,738,468
Total liabilities		5,270,515	6,738,468
Net assets		15,521,019	13,756,553
Funds			
Accumulated surplus	12	15,521,019	13,756,553
Total funds		15,521,019	13,756,553

The above statement of financial position should be read in conjunction with the accompanying notes.

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Statement of changes in funds

For the year ended 30 June 2022

	Accumulated Funds \$	Total Funds \$
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	-	-
Total comprehensive income for the year	13,756,553	13,756,553
Balance at 1 July 2021	13,756,553	13,756,553
Surplus for the year	1,764,466	1,764,467
Other comprehensive income for the year	-	-
Balance at 30 June 2022	15,521,019	15,521,019

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

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Statement of cash flows

For the year ended 30 June 2022

	Note	2022 \$	2021 \$
Cash flows from operating activities			
Receipts from government grants, other funding and other revenue		16,766,174	19,729,335
Payments to funding recipients, suppliers and employees		(16,939,006)	(12,347,193)
Interest received		86,368	89,054
Net cash flows from operating activities	13	(86,464)	7,471,196
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		(86,464)	7,468,534
Cash and cash equivalents at beginning of year		20,435,562	12,967,029
Cash and cash equivalents at end of year	5	20,349,098	20,435,563

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

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

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 – Simplified Disclosures, Accounting Interpretations 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 2022.

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.

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

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) 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.

(d) Expenditure

All expenditure is accounted for on an accruals basis.

(e) 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.

(f) 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.

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Notes to the financial statements (continued)

1. Significant accounting policies (continued)

(g) Cash and cash equivalents

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

(h) 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

(i) 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.

(j) 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.

(k) Trade and other receivables

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

(l) Trade and other payables

Trade and other payables are stated at amortised cost.

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Notes to the financial statements (continued)

1. Significant accounting policies (continued)

(m) Critical accounting estimates and judgements

The Board Members evaluate estimates and judgements 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.

2. Revenue from operations

Revenue from contracts with customers – AASB 15

	2022 \$	2021 \$
Government funding	1,767,060	401,600
Funding and grants from corporate and institutional funding bodies	2,240,287	4,460,113
	<u>4,007,347</u>	<u>4,861,713</u>

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	1,459,743	800,695
Donations	925,000	150,100
Other revenue	-	24,852
	<u>12,384,743</u>	<u>10,975,647</u>

Total revenue from operations	<u>16,392,090</u>	<u>15,837,360</u>
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Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Notes to the financial statements (continued)

	2022 \$	2021 \$
3. Service provider and projects expenses		
Amounts paid or distributed to service providers for projects	12,584,110	11,515,568
	<u>12,584,110</u>	<u>11,515,568</u>
4. Consulting and support services expenses		
Consulting and administration	504,667	671,142
Legal costs	100,428	41,675
Other costs	49,647	71,623
	<u>654,742</u>	<u>784,440</u>
5. Cash and cash equivalents		
Cash at bank	20,349,099	20,435,563
	<u>20,349,099</u>	<u>20,435,563</u>
6. Receivables		
Trade receivables	265,811	32,100
ATO receivable	140,422	-
	<u>406,233</u>	<u>32,100</u>
7. Other assets		
Accrued revenue	35,315	25,583
	<u>35,315</u>	<u>25,583</u>
8. Plant & equipment		
Computer equipment	2,662	2,662
Accumulated depreciation	(1,775)	(887)
	<u>887</u>	<u>1,775</u>
9. Contract liability		
Income received in advance	3,435,507	4,598,400
	<u>3,435,507</u>	<u>4,598,400</u>

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Notes to the financial statements (continued)

	2022	2021
	\$	\$
10. Trade payables and accruals		
Trade and other payables	546,389	414,273
ATO payable	-	205,094
Accruals	1,230,928	1,488,884
	1,777,317	2,108,251
11. Provision		
Provision for employee leave entitlements	57,691	31,817
	57,691	31,817
12. Accumulated funds		
Accumulated funds at the beginning of the financial year	13,756,552	10,591,071
Surplus for the year	1,764,467	3,165,482
Accumulated funds at the end of the financial year	15,521,019	13,756,553
13. Reconciliation of cash flows from operating activities		
Surplus for the year	1,764,467	3,165,482
Add: depreciation	887	887
Changes in assets and liabilities		
Change in receivables	(374,133)	212,876
Change in other assets	(9,732)	(15,835)
Change in contract liability	(1,162,893)	2,098,400
Change in trade and other payables	(330,933)	1,977,569
Change in provisions	25,874	31,817
Cash flows from operating activities	(86,464)	7,471,196
14. Auditor remuneration		
Audit services – Grant Thornton	23,000	19,700
	23,000	19,700
15. Contingencies		
The Company had no contingent liabilities as at 30 June 2022 and 30 June 2021.		

Australian Genomic Cancer Medicine Centre Limited
30 June 2022

Notes to the financial statements (continued)

16. 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.

17. Related party transactions

Key Management Personnel Compensation

The Company paid \$368,148 to key management personnel during the year (2021: \$316,379). There were no other transactions with key management personnel during the year ended 30 June 2022. 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. Nathan McGregor is the appointed Director of this Company, by the Garvan Institute of Medical Research. The previous appointed Director, Professor Chris Goodnow, resigned during the year. 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, \$848,323 (2021: \$1,282,965) 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, \$4,551,313 (2021: \$2,982,500) 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, \$196,691 (2021: \$206,362) was received from Garvan Institute of Medical Research as part of this funding.

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

**Australian Genomic Cancer Medicine Centre Limited
30 June 2022**

Notes to the financial statements (continued)

report, the terms of the Research Agreement and the Licence to Occupy Agreement with Garvan Institute of Medical Research are in the process of being amended. Refer to Note 18 for details.

17. Related party transactions (continued)

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, \$4,451,940 (2021: \$4,439,303) was paid to that entity by this Company under this agreement. An additional \$1,036,911 was paid to the University for drugs, test kits and logistics.

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. \$500,000 (2021: 1,500,000) 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 \$755,000 (2021: \$716,250) to BioGrid Australia Limited as part of this agreement.

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, who resigned from the Board during the year, was 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 \$22,000 was made in the year (2021: \$20,000) 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 \$789,650 has been made in the current year (2021: \$344,550) towards research services provided by University of Melbourne.

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.

There were no other related party transactions during the year ended 30 June 2022.

**Australian Genomic Cancer Medicine Centre Limited
30 June 2022**

Notes to the financial statements (continued)

18. Events subsequent to balance date

The Company is in discussion with Garvan Institute of Medical Research to vary the terms of the Licence to Occupy Agreement and the Research Agreement for the remaining two years of these agreements. As at the date of this report, these discussions are in progress and hence a financial estimate of the resulting changes cannot be made. In the Directors' assessment, the likely financial impact of these changes will not be material to the future operation and financial position of the Company. There are no other material events subsequent to balance date.

19. 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.

20. 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.

**Australian Genomic Cancer Medicine Centre Limited
30 June 2022**

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 2022

**Australian Genomic Cancer Medicine Centre Limited
30 June 2022**

Responsible Entities' Declaration

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

1. The financial statements of AGCMC are in accordance with the Australian Charities and Not-for-profits Commission Act 2012 including:
 - a. giving a true and fair view of its financial position as at 30 June 2022 and of its performance for the financial year ended on that date;
 - b. complying with Australian Accounting Standards – Simplified Disclosure and the Australian Charities and Not-for-profits Commission Regulation 2013; and
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:

DocuSigned by:



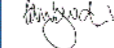
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Paul Jeans
Chair of the Board of Directors

Sydney

26 August 2022

DocuSigned by:



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Bruce Goodwin
Director

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 2022, 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 2022

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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 2022, 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:

- giving a true and fair view of the Registered Entity's financial position as at 30 June 2022 and of its financial performance for the year then ended; and
- 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.

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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 in accordance with the Charitable Fundraising Act 1991 but does not include the financial report and our auditor's report thereon.

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 2022



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Australian Genomic Cancer Medicine