Outsmarting cancer, together

Annual Report 2023

Omico.

What we achieved in 2022/2023:

Established the Precision Oncology Screening Platform Enabling Clinical Trials (PrOSPeCT):

- $185m in public and private funding
- 23,000 patients to have access to genomic profiling, clinical assessment and matching to the best advanced precision ('personalised') treatments available locally
- creating an estimated 650 high-skilled local jobs
- stimulating $525M investment in local clinical trials
- driving $135M in savings to the health system
- building a real-world biodata platform

prospect.

CaSP Cancer Screening Program

Molecular screening program underpinning PrOSPeCT:

Started counting from 17th March 2023

At the end of September 2023:

- 1232 patients enrolled
- 590 Molecular Oncology Board reports sent to treating oncologists
- 425/590 patients with a matched treatment/therapy recommendation

MoST patients screened

at September 2022: 5749

at September 2023: 6966

Patients receiving a matched therapy after molecular screening (CaSP and MoST)

1075 (20%)

MoST patients on novel therapy studies

at September 2022: 504

at September 2023: 714

Pharmaceutical industry MoST support

$20.2m

in-kind support medicines to treat 920 patients

MoST substudies

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

at September 2023: 1 closed; 14 in follow-up; 9 recruiting 1 in start up; 30 referring+

Philanthropic support for MoST substudies

$4.0m

MoST subprograms

pan cancer

lung cancer

blood cancer

pancreatic cancer

RisC participants enrolled

at September 2022: 1758

at September 2023: 2092

SMOC+ participants enrolled

at September 2022: 153

at September 2023: 187

MoST recruiting sites

6 member sites

15 other sites across Australia (plus NZ)

RisC probands sequenced

at September 2022: 1570

at September 2023: 1570*

SMOC+ cancer detection

44 new primary cancers in 31 (18%) individuals

* next batch of samples sent for sequencing in September 2023

+ platform support for recruitment to company sponsored trials trials

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 with cancer
- by accelerating the use of precision oncology
- and growing clinical trials
- and modernising the Australian healthcare system

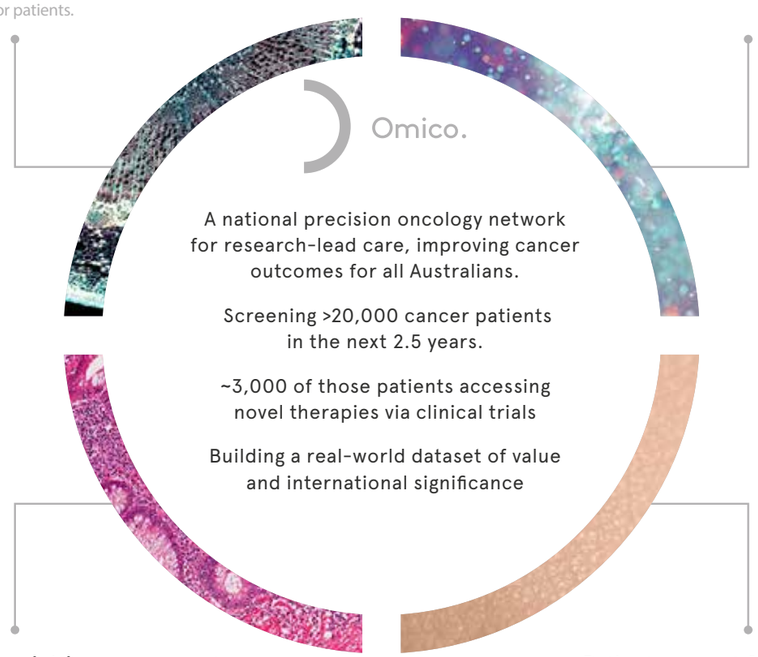
Our mission focuses on these four pillars:

Molecular screening & therapeutics

Tumour profiling to evaluate biomarker-driven treatments for patients.

Health system reform

Leading health system reform through evidence.



Personalised risk management

Using heritable genetic information to assess cancer

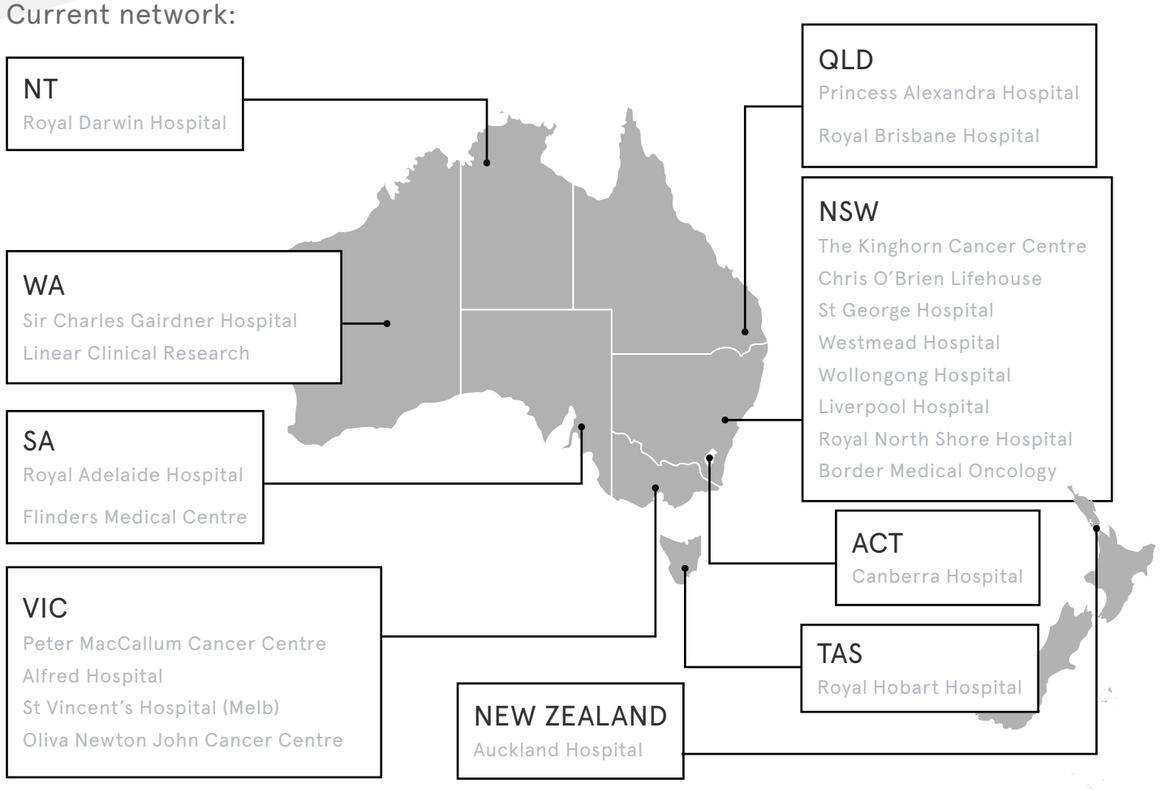
Patient support & advocacy

Supporting patients and families today and planning

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.

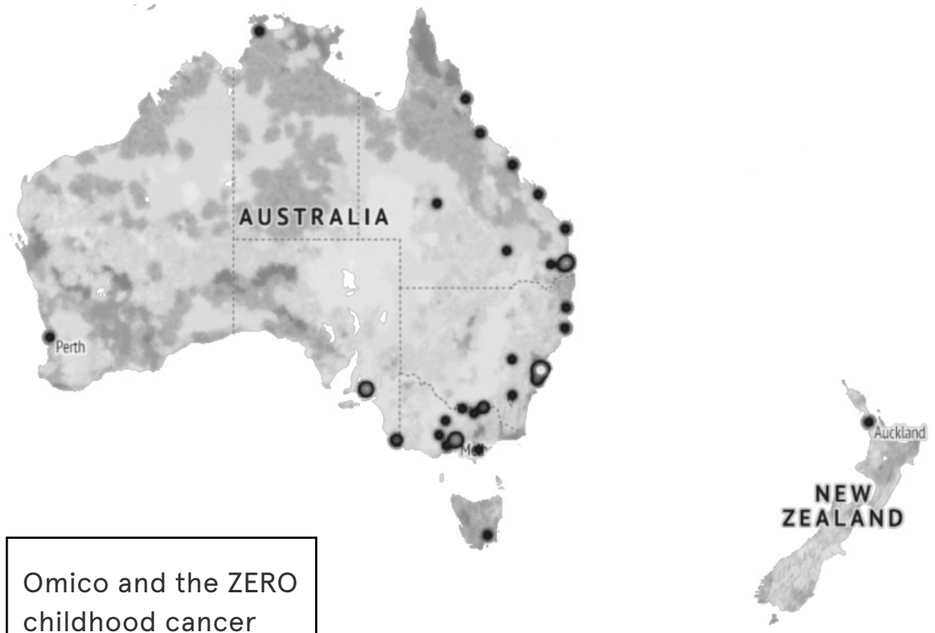
Current network:



Omico Members

Our National Clincial Trials Network

Omico is expanding its network of cancer treatment centres around the nation.

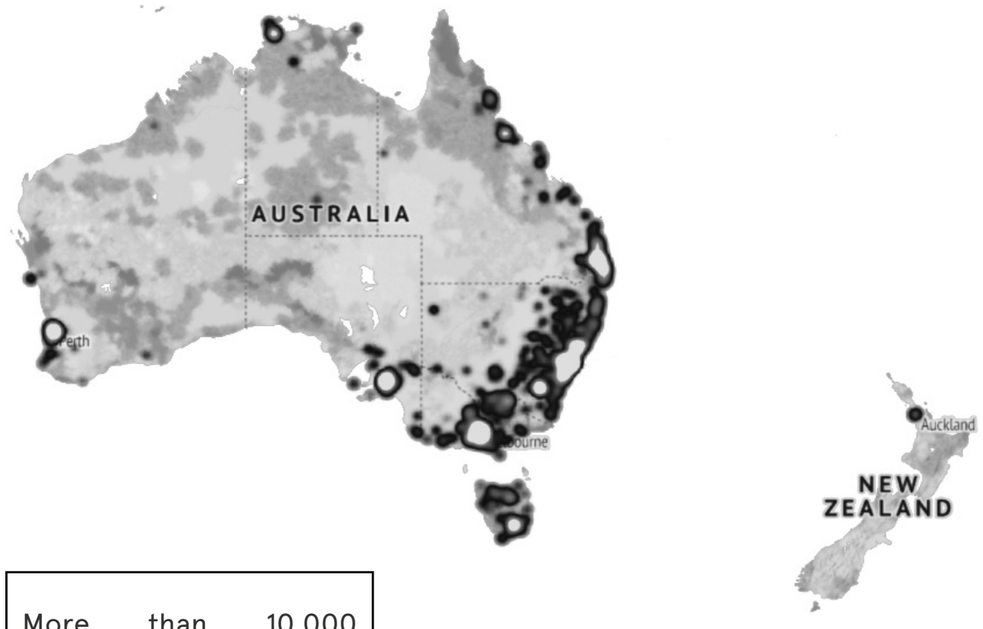


Omico and the ZERO childhood cancer program cover more than 48 clinical trials sites across Australia and New Zealand

Google Maps® - heat map presenting the location of treatment centres across Australia

Our Patient Reach

Patients are recruited from across the nation.



More than 10,000 patients recruited into the screening program to date. This will grow to more than 35,000 adults and children screened by 2025.

Google Maps® - heat map representing the postcodes of the more than 10,000 patients screened by our programs to date

Some of Our Partners

Prospect Foundational Partners

Omico.
Roche
NCI
Children's Cancer Institute

Key Industry Partners

MSD
Pfizer Oncology
AstraZeneca
Boehringer Ingelheim
FOUNDATION MEDICINE
Medicines Australia
Hummingbird Bioscience
SERVIER Oncology

plus many others

Other industry and public sector Prospect partners include:

SYNTRO
PeterMac Peter MacCallum Cancer Centre Victoria Australia
SONIC HEALTHCARE
BIOPLATFORMS AUSTRALIA
PRAXIS AUSTRALIA
George Clinical
MICROBA
illumina
Southern Star RESEARCH
quantium
BAYER

Collaborators

rare cancers AUSTRALIA
BioGrid
MACQUARIE University SYDNEY-AUSTRALIA
NSW Health Pathology
Australian Genomics Health Alliance
canteen
QIMR Berghofer Medical Research Institute
Leukaemia Foundation
Minderoo Foundation
DOUGLASS HANLY MOIR PATHOLOGY
ATGC Australian Translational Genomics Centre
CRBF
UNSW SYDNEY

International molecular profiling studies

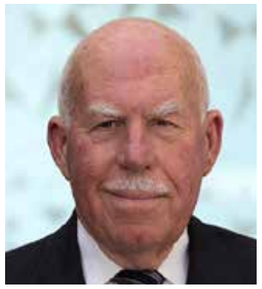
ASCO Tapur (USA)
CAPTUR (Canada)
DRUP (Netherlands)

Government supporters include:

Medical Research Future Fund
Australian Government Department of Industry, Science and Resources
NSW Government Health
Australian Government Department of Health
NSW Government Investment NSW

Our People

Our board



Mr Paul Jeans

Board Chair

Mr Richard Vines*

Deputy Chair

Professor David Thomas*

CEO

Professor Benjamin Kile

(for Garvan Institute of Medical Research)

Mr Bruce Goodwin*

Professor John Simes

(for University of Sydney)

Ms Sue MacLeman

Professor Michael Brown

(Member representative)

Professor Ricky Johnstone

(Member representative)

Ms Tze Masters*

A/Professor Paul Martin

Company Secretary

*Finance, Risk and Audit Committee members, Ms Tze Masters chair of the committee from September 2022

Our leadership team

Professor David Thomas

CEO

Dr Vera Terry

Deputy CEO

Mr Waman Tamhankar

CFO

Dr Mandy Ballinger

Head of Cohorts

Kym Bramich

Head of Marketing & Communications

Dora Ardila

Medical Advisor

Ronald Chan

Chief Data Officer

Dr Lucille Sebastian

National Clinical Trials Network Program Manager

Karishma Jivani

Head Business Development

Matt Britland

Business Development

Our Objectives

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

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

> A not for profit company, limited by guarantee

The Objectives of Omico are to:

1. expand the Molecular Screening and Therapeutics (MoST) and Cancer Risk in the Young (RisC and SMOC+) Programs;
2. expand the MoST study so as to provide genomic testing and access to collaborative clinical trials for Australians with advanced, incurable, rare and less common cancers across Australian centres of excellence in cancer research and treatment;
3. provide a framework for standardised consent, biobanking of tumour material and genomic profiling;
4. make biobanked material available for further research;
5. support the collection, 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.

We are changing the way we fight cancer by accelerating access to precision oncology, improving outcomes for Australians.

Report from the Chair and CEO

Dear Colleagues

This has been a year to remember, full of activity and tremendous progress. Whilst continuing existing programs, we have commenced our landmark initiative, PrOSPeCT (Precision Oncology Screening Platform Enabling Clinical Trials), expanded our team and external partnerships, and physically moved to a new home. We want to acknowledge the incredible effort from the executive and clinical teams in making all of this happen – our heartfelt thanks to you all.

PrOSPeCT

Our landmark initiative, PrOSPeCT, commenced March 2023. This is the largest precision oncology initiative in Australia; an extraordinary approach that will enable 23,000 Australians with advanced or incurable cancers to access Comprehensive Genomic Profiling (CGP) and matching to novel, targeted treatments via clinical trials. In this, it will also stimulate Australian research by expanding the number of clinical trials in Australia through direct investment by the global pharmaceutical sector.

Omico is proud to lead this pioneering initiative involving public-private partnerships, a national network of Australia's world-class cancer institutes, researchers, industry partners, patient organisations and government, and $185M of funding. Grant funding of $61.2M was approved in early 2022 from the Federal Department of Industry Science and Resources (DISR) as part of the Modern Manufacturing Strategy. We were delighted that the Labour Government reconfirmed this in September 2022.

Omico is grateful for the many partners and stakeholders enabling PrOSPeCT. Our Foundational partners - Roche Products Australia, National Computational Infrastructure (NCI) and Childrens' Cancer Institute - deserve a very special mention not only for their significant financial contribution but also for their strong commitment and involvement in the governance of PrOSPeCT.

Highlights of PrOSPeCT progress to date include:

Official launch held 27 July 2023, attended by the Hon Emma McBride MP, Assistant Federal Minister for Mental Health and Suicide Prevention and, Assistant Federal Minister for Rural and Regional Health and the Hon Ryan Park MP, NSW Minister for Health. Attendance and media coverage was significant, raising the awareness or PrOSPeCT.

The Clinical team have worked tirelessly to establish CaSP, PrOSPeCT's Cancer Screening Program. Since 1 October 2022 the cohort operations team has expanded from 23 to 52 to accommodate the demands of PrOSPeCT. We anticipate an additional ~35 individuals in 2024. We thank the team for their excellent achievements to bring PrOSPeCT to life, including:

- the team has established new software infrastructure and driven process improvements to increase efficiency, and convenience and clarity for patients.
- patient referrals to CaSP are above forecast, at 1,658 referrals with 1,232 patient consents and 590 MOB reports generated with an average turn-around time of 7-8 weeks.

Activation of pathology and sequencing laboratories: Working relationships established with 7 sequencing laboratories, contracts negotiated with national pathology service providers to supply and cut tissue and collect bloods, and protocols and SOPs established at NSW Statewide Biobank for CaSP research blood sample receipt, processing, storage and data transfer. We thank Mandy Ballinger and her team for these critical steps and significant achievements to enable PrOSPeCT.

Omico's Business Development function and National Clinical Trial Network are key to building the number of clinical trials supported by PrOSPeCT. Since March 2023, there are now 33 (recruiting or in start up) precision oncology clinical trials in partnership with several pharmaceutical, biotech and clinical research organisations, with a growing pipeline. We acknowledge Matt Britland, our BD lead, for his focussed efforts to build these opportunities.

In addition, our National Clinical Trial Network has expanded from 22 to 43 sites over the last year, an incredible achievement. Lucille Sebastian assumed her role as National Clinical Trial Program Network Manager in July 2023, and is further expanding relationships and the number of clinical trials sites across Australia. Importantly, the first Praxis-led traineeship for increasing clinical trial staff capability will kick off in October with a full registration of 20 participants, of which more than half are from regional centres.

Impact on Industry growth: Our commitment to DISR includes driving economic, capacity and employment growth in the research sector. Thanks to the combined efforts of our partners, we're proud to share the positive impact includes a $2.6M investment in research and development and 55 new jobs in the first 6 months of the program.

PrOSPeCT has attracted interest from both local and international clinical communities, given the uniqueness of this platform and importance of accelerating access to precision oncology. We are pleased with the achievements so far and the momentum gained. We thank every organisation and person who is on the journey with us and know that we can count on you as we work together to make further progress.

Research Programs

The MoST program continues to deliver above expectations and now has almost 7,000 patients enrolled, an increase of 1,100 over the last year. Of these patients, 714 have commenced participation in clinical trials of novel therapies. We acknowledge more than 400 clinicians who continue to refer patients to this program, which is clearly providing an important clinical pathway for patients with advanced cancers.

Our preliminary analyses of MoST shows that patients who receive a therapy closely matched to a biomarker identified in their tumour have a more than doubling of their expected survival. The learnings and success of MoST have been the basis for PrOSPeCT, given the demonstrated importance of CGP and personalised therapy in improving outcomes for patients with difficult-to-treat cancers.

The ASPiRATION subprogram of MoST reached it's 1,000 patient recruitment milestone on 21 June 2023, with 52% having an actionable lung cancer biomarker linked to a targeted therapy. Our collaboration is ongoing with TOGA, Roche and the NHMRC CTC to ensure that the 1,000 patient dataset is available for preliminary analysis in Jan 2024. Pleasingly, TOGA's submission to publish the ASPiRATION protocol was accepted by Future Oncology.

The RisC and SMOC+ programs continue to run on track. In the past year, RiSC has enrolled a further 320 individuals who have been diagnosed with cancer before the age of 40 years, bringing the total enrolment to 2,092. SMOC+ has enrolled a total of 187 people, 32 in the last year, who are at extreme cancer risk. SMOC Junior, a childhood version, commenced November 2022 for children at extremely high cancer risk. Six participants are enrolled, with a new primary cancer identified in one participant who is now being treated. SMOC Junior will expand to John Hunter Children's Hospital and Westmead Children's Hospital in 2024.

We congratulate our hard-working clinical teams, led by Drs Mandy Ballinger, John Grady, Frank Lin, Beverley Murrow, Laura Manuel, Audrey Silvestri, Jenny Gu, Olivia Turnbull, Subo Thavaneswaran, Christine Napier, and Lucille Sebastian, for these remarkable achievements.

Our research has impact - 120 publications to date, including the publication of a high impact Science paper where Ballinger, M. et al. have created the first genetic map to identify important genes that cause sarcoma.

Based on our research data, Omico made a submission to the Medical Services Advisory Committee to fund access through the MBS to whole body MRI for patients with Li Fraumeni syndrome. The Medicare item number for annual whole body MRI for TP53 variant carriers was approved from 1 March 2023. This will change forever the options available to LFS families.

Following an invitation from the Senate Community Affairs References Committee, Omico made a submission in September 2023 to the Senate Inquiry into the equitable access to diagnosis and treatment for individuals with rare and less common cancers, including neuroendocrine cancer. We hope to further participate in the inquiry, which is due for report in March 2024.

A new home for Omico

Since 2018, Omico has been privileged to be located at the Garvan Institute in Darlinghurst. Our team has enjoyed the bright physical environment and talented colleagues at this institute. We thank the Garvan leadership team for hosting our organisation and look forward to our strong and productive relationship continuing.

In June 2023, Omico commenced our re-location to join the esteemed institution of UNSW. We thank

the UNSW for their warm welcome to the vibrant co-location community at UNSW, Kensington Campus. Our expanding operations team is currently navigating across both Garvan and UNSW sites, and we thank them for their agility as we establish our new home. Most staff will transition to UNSW employment on January 1, 2024.

We would like to acknowledge and thank our Omico board members for their ongoing support and governance, always demonstrating strong commitment to Omico's success. A very special thank you to Bruce Goodwin who was extremely effective as Acting CEO for several months whilst David Thomas managed a significant health issue. David continued strong contribution to Omico despite this health setback, and we are delighted to have him back at full capacity now.

Omico is also extremely thankful to its Members, as their support is invaluable as we continue to grow and expand. We are so grateful that both the Members and the Board approved the PrOSPeCT initiative mid-2022, which has enabled Omico to strengthen its impact for patients, communities and industry.

There is no doubt that Omico has already contributed directly to improving health benefits for Australians with cancer. However, we also know only 8% of all cancer patients in Australia have access to clinical trial options, so critical to access to a novel therapy to improve their outcomes.

With PrOSPeCT, we hope to improve outcomes for these under-served patient populations, in a sustainable way that also grows the economy. We look forward to continuing to work with you all to bring new options for these patients for the long term. Thank you for joining us on our mission.

Mr Paul Jeans (Chair of the Omico Board)

Professor David Thomas (CEO)

Cancer
meets its match

Omico.

PrOSPeCT
– a landmark initiative

(Precision Oncology Screening Platform Enabling Clinical Trials)

Prospect will broaden the possibilities for its partners and for patients

$525M

New direct investment in locally based clinical trials

$135M

Savings from avoided health interventions (medicines, tests, hospitalisations)

23,000

Patients accessing cutting-edge genomic screening

>650

Jobs created in genomics, clinical trials and diagnostics in two years

Precision oncology has revolutionised our ability to fight cancer more than ever before.

Precision oncology uses genomic profiling (screening) to detect unique genetic variations in cancer patients' tumours, enabling us to predict, prevent, diagnose and treat cancer at an individual level.

At Omico, we are providing Australian patients with advanced or incurable cancer accelerated access to free comprehensive genomic profiling, enabling us to potentially match them to clinical trials with new targeted therapies faster for improved outcomes.

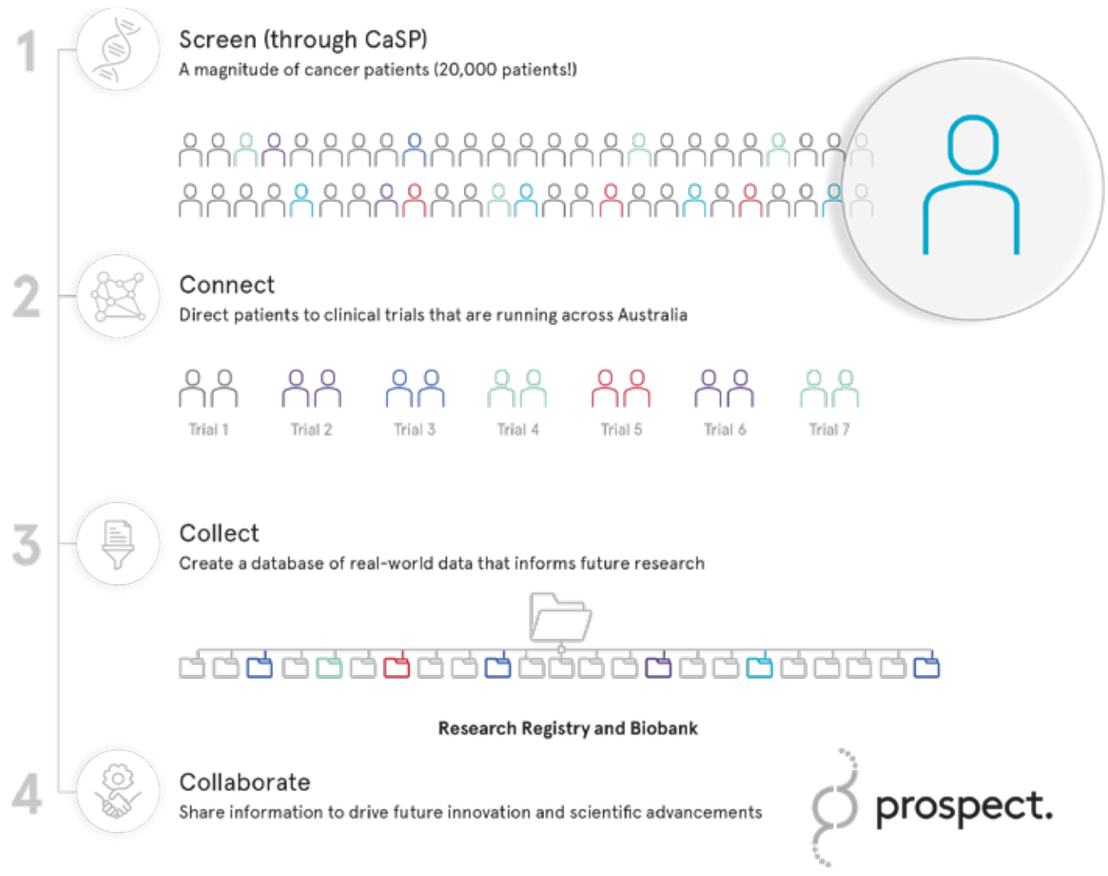
The Precision Oncology Screening Platform Enabling Clinical Trials (PrOSPeCT) is a world-leading initiative, which will enable Australia to tap into the global cancer research market — currently valued at more than A$130B.

PrOSPeCT is enabled by public-private funding and partnerships, totalling over $185M, including $61.2 million in grant funding from the Australian Government as part of the Modern Manufacturing Strategy and $25M from the NSW Government.

Over 27 months, PrOSPeCT's Cancer Screening Program (CaSP) will provide free genomic profiling to 23,000 Australians with advanced or incurable cancers and identify potential matches for patients to clinical trials with new targeted therapies.

PrOSPeCT is the largest cancer genomics initiative in Australia.

prospect.



Research Highlights

Cancer Screening Program (CaSP)

Cancer Screening Program (CaSP) is a public-private partnership enabling the matching of cancer patients to clinical trials. There are four components of CaSP:

- free Comprehensive Genomic Profiling (CGP) for more than 23,000 patients with advanced and incurable cancer
- an integrated Molecular Oncology Board (MOB), which reviews clinical and CGP results, documents potential treatment and clinical trials options for patients and provides this information to the referring doctor
- long term follow-up of patients and their referring doctor as part of an observational cohort study of people enrolled in CaSP
- a Research Registry and Biobank that facilitates ongoing research into cancer and its treatment

CaSP is the molecular screening and clinical trials matching platform for PrOSPeCT.

Omico is working with its partners (pharmaceutical partners, governments, the clinical and academic community, contract research organisations, workforce training, and the public) to establish a long-term business model which will increase access of all Australian cancer patients to genomic profiling and clinical trials, both commercial and academic. Omico is also working with its partners to enhance

> Molecular screening for Australian cancer patients

workforce training and education, rural and regional clinical trials access, and access of indigenous cancer patients to genomic profiling and clinical trials.

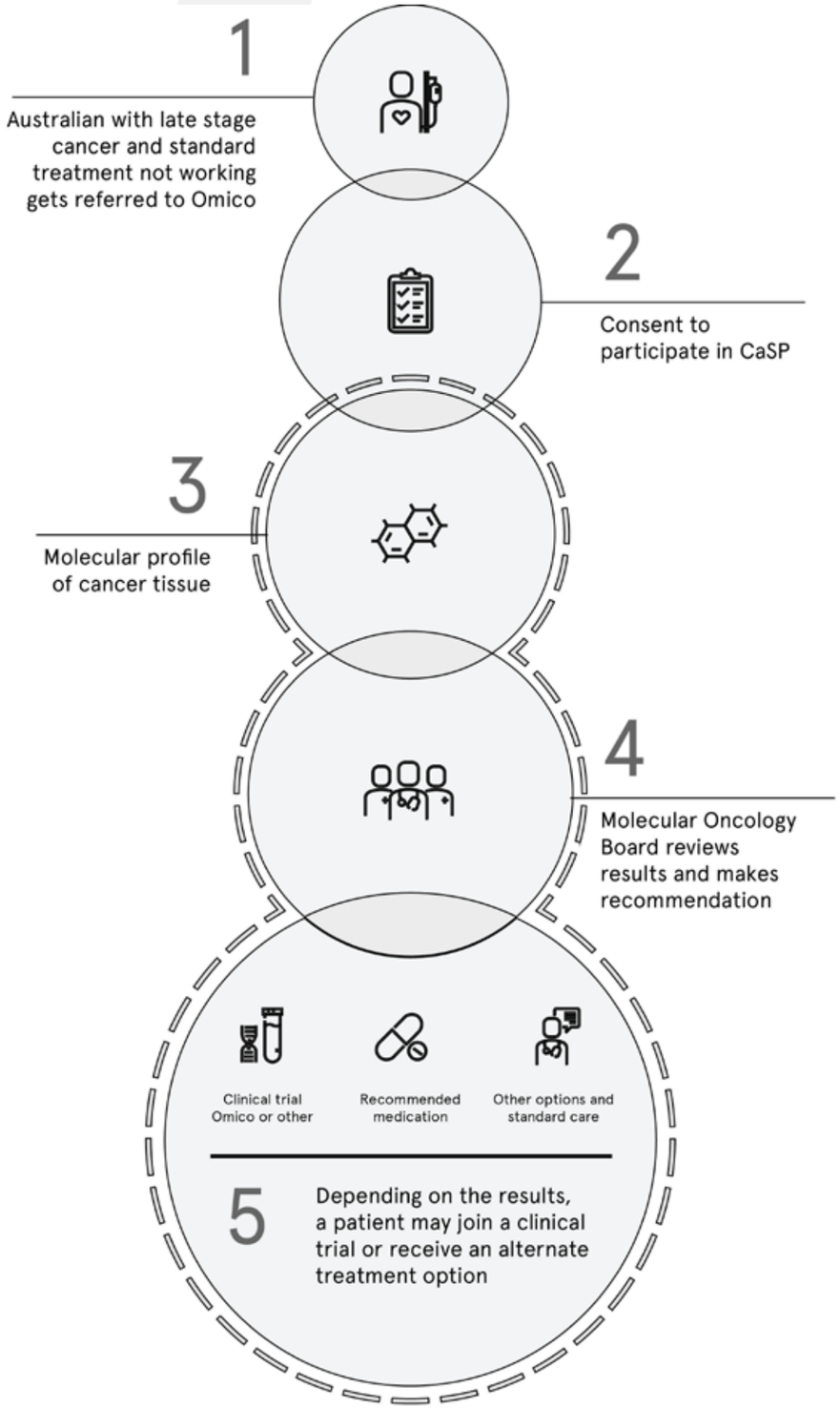
Children and adolescents with high-risk cancers are enrolled onto the ZERO Childhood Cancer national precision medicine program (ZERO).

Progress from 17 March to 30 September 2023:

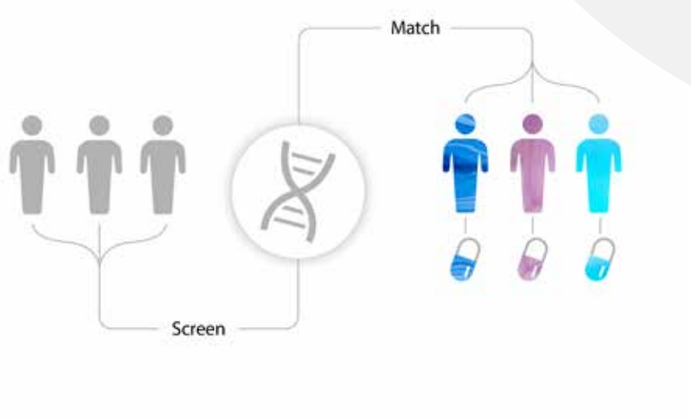
1441
patients enrolled
1231 into CasP and 209 into ZERO

684
Reports sent to referring clinicians
590 (adult) and 94 (paeds)

457
Patients with matched treatment/ therapy recommendations
425/590 (adult) and 32/94 (paeds)



Molecular Screening and Therapeutics Program (MoST)



The MoST Program will continue to deliver molecular screening and trials matching to advanced cancer patients to the end of 2023.

On the close of the screening component of MoST patients will be enrolled and consented to the Cancer Screening Program (CaSP) for molecular profiling. Trials matching will be unaffected by the change.

Recruitment to the screening component of the Molecular Screening and Therapeutics (MoST) program has exceeded expectations, influencing the establishment of CaSP.

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

During 2023 we continued recruiting to the pan and blood cancer groups, and closed recruitment to the lung and pancreatic cancer groups.

The 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 were identified from within the current MoST screened cohort.

MoST pan cancer cohort screening update:

In total, over **6966** (including 188 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 42% 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, **188 New Zealanders** have enrolled into the NZ MoST counterpart.

ASPiRATION lung cancer cohort:

After a delayed start due to COVID-19, **1000** newly diagnosed metastatic, non-small cell lung cancer patients were enrolled onto the ASPiRATION subprogram by June 2023. 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, **56 lymphoma and 49 leukaemia** patients have enrolled into the cohort. Funding support from the Leukaemia Foundation, Tour de Cure, MRFF and other philanthropic bodies have provided **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). More than 400 pancreatic patients have been referred to the program with **300 patients** enrolled into the cohort between January 2022 and July 2023.

Updated results from the MoST cohort:

1 in 3

(38%) patients screened received recommendations for matched therapies[1]

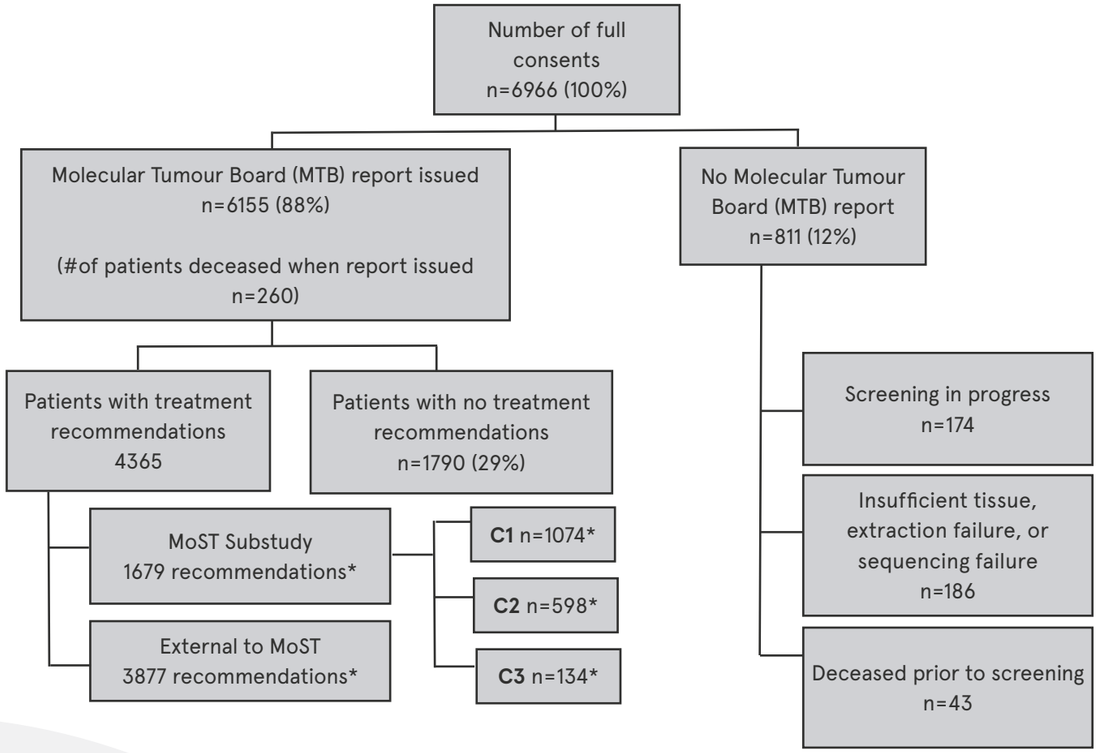
~50%

Improved survival rate with matched therapy[1]

1. Genomic therapy matching in rare and refractory cancers: Updated results from a retrospective cohort study in the Molecular Screening and Therapeutic (MoST) program. (2023) FPY Lin, S Thavaneswaran, CE Napier, JP Grady, M Kansara et al. Journal of Clinical Oncology 41 (16_suppl), 1540-1540 presented at ASCO 2023

Pan cancer patients enrolled in MoST by state, and New Zealand (as at September 2023)

About the MoST pan cancer cohort:



Of the 6966 patients enrolled, 6155 (88%) have had an MTB report issued. 3709/6966 (53%) patients are deceased, with 303/3709 (8%) deceased prior to the completion of molecular screening.

Treatment recommendations have been made to 4365 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.

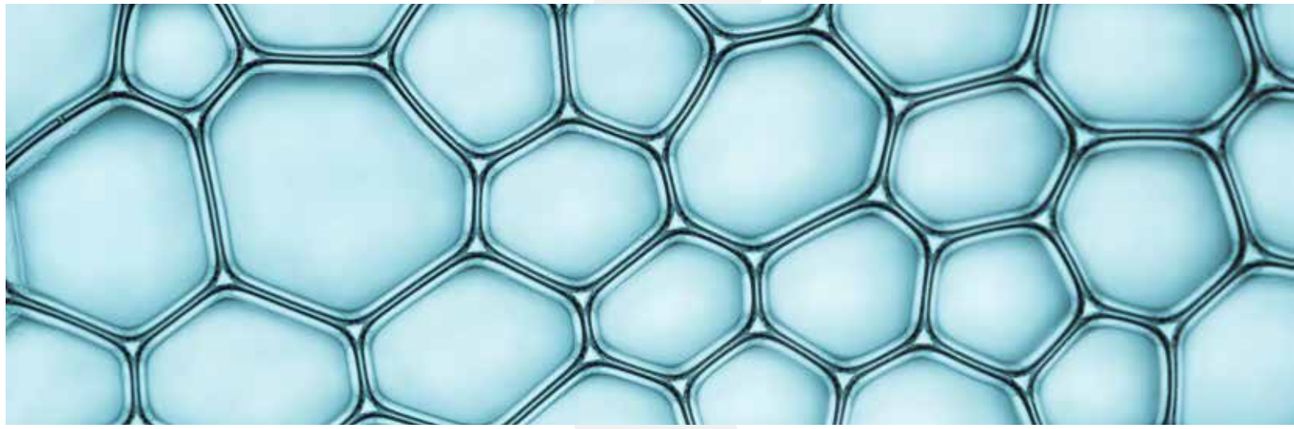
MoST Companion Studies (C2) - these studies are collaborations between Omico and other groups or organisations that leverage the MoST screening program and complement the therapeutics program. For example, MoST CIRCUIT - a collaboration with the Olivia Newton John Cancer Research Centre (ONJCRI) on an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

Current clinical study pipeline status:

MoST Substudies (C1) in recruitment or follow-up:		Recruitment Status	Recruitment/target
1.	Palbociclib	closed	16/16
2.	Durvalumab and Tremelimumab (pan cancer)	closed	65/65
2+	Durvalumab and Tremelimumab (pan cancer) expansion	closed	49/49
3.	Olaparib and Durvalumab	closed	49/49
4.	Vismodegib (pan cancer)	closed	16/16
5.	Eribulin (pan cancer)	closed	16/16
6.	Larotrectinib (pan cancer)	closed	16/32
7.	Tremelimumab (pan cancer)	closed	22/24
8.	Trastuzumab emtansine (Kadcyla) (pan cancer)	closed	32/32
8+	Trastuzumab emtansine (Kadcyla) (ASPiRATION) + and 2nd line lung -mNSCLC	recruiting	17/32
9.	Tucatinib and trastuzumab (pan cancer)	recruiting	31/32
10.	Palbociclib plus avelumab (pan cancer)	closed	64/64
11.	Tildrakizumab (pan cancer)	closed	32/32
12.	Vemurafinib and cobimetinib (combined pan cancer and ASPiRATION)	recruiting	50/64 (25 pan cancer, 25 ASPiRATION)
13.	Entrectinib (combined pan cancer and ASPiRATION)	closed	0/16
14.	Alectinib (pan cancer and ASPiRATION)	recruiting	13/16 (9 pan cancer, 4 ASPiRATION)
16.	Pamiparib (haematology)	recruiting	8/16
17.	Tepotinib (ASPiRATION)	closed	8/32
18.	Durvalumab plus chemotherapy (pan cancer)	closed	6/16
19.	Sotorasib (AMG510) (pan cancer)	recruiting	2/32
20.	Seribantumab (pan cancer)	closed	3/16
MoST Companion studies (C2)			Target number
1.	MoST CIRCuit (pan cancer)	recruiting	185/240
2.	MoST Porcupine2 (RXC004) (pancreas cancer)	closed	5/8
3.	SPEAR (pancreas cancer)	recruiting	4/32
4.	MoST TAP (atezolizumab and tiragolumab) (pan cancer)	in start up	0/96
MoST Company studies (C3)			Target number
	we are currently supporting 30 company sponsored clinical trials	referring	201 referrals made to C3 trials under MoST



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.

Substudy update:

1 closed
14 in follow-up
9 recruiting
1 in start up
30 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 been consistent - 202 patients enrolled into MoST C1 and C2 studies between September 2022 and September 2023, bringing the total to **717**.

Key achievements of the molecular therapeutics program to 30 September 2023

Number of patients enrolled onto the therapeutics program from January 2019:

- **C1 & C2** Studies: **587**

Number of patients enrolled onto the therapeutics (C1&C2) program from September 2016: **717**

Status Update:

- many studies have either met their recruitment targets or activities are being rationalised in consultation with supporting partners, especially for rare population molecular subtypes.
- 8 of studies that have completed accrual and have publications in press or in draft.
- 6 studies have closed to recruitment in consultation with the commercial partners prior to reaching their recruitment target.
- We anticipate all of the recruiting C1 studies will be closed by the end of 2024 with patients completing treatment and follow up during 2025.

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

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

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 >9,000 patients and resulted in matched treatment decisions for more than >1000 patients

Established partnerships

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

Support from a strong consortium

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

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.

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.

Recent follow up attempts:

- 3369/3617 (93%) of patients have had at least one successful follow up attempt
- There were 8071 attempts at follow, with 5783 completed (72%)

Matched therapies:

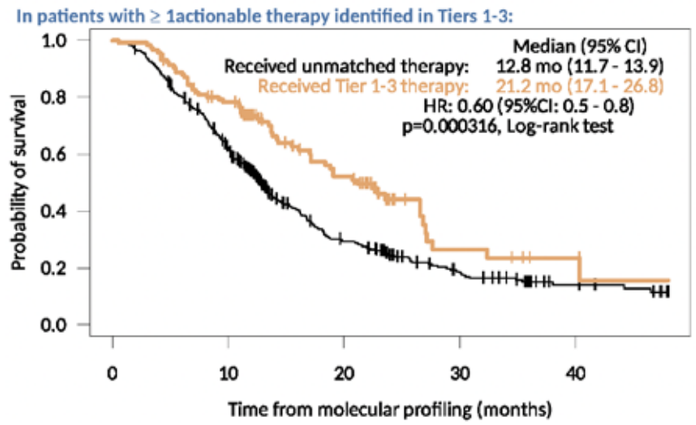
1026 matched therapies were received by 782 MoST & ASPiRATION patients after sequencing was completed.

Of the 1026 matched therapies received:

- 792/1026 (77%) were based on molecular profiling
- 194/1026 (19%) based on standard of care results
- 40/1026 (4%) were clinical decisions prior to molecular profiling

Of the 1026 matched therapies received:

- 213/1026 (21%) via a clinical trial
- 381/1026 (37%) via a MoST Substudy
  - C1 – 357/381 (94%)
  - C2 – 22/381 (5%)
  - C3 – 2/381 (1%)
- 111/1026 (11%) via compassionate access
- 84/1026 (8%) privately funded
- 75/1026 (7%) via PBS
- 162/1026 (16%) unknown access method



Survival curve of all MoST pan cancer patients, sorted by those that received a matched therapy and those who did not.

Some of the patients we have helped

Patient

Female, early 70’s

Diagnosis

Lung cancer

A woman in her early 70’s from regional NSW. She has never smoked, and has a large extended family. The routine testing of her tumour did not find any genetic change that could account for the growth of her lung cancer.

Fortunately, she was referred to the ASPiRATION program, a study providing tumour sequencing for patients with newly diagnosed metastatic lung cancer. Her ASPiRATION results showed a genetic change that was causing her tumour to grow. She then accessed a drug via the PBS that is selectively targeting cancer cells with this specific genetic change. Seven months later, she is doing very well, her tumour is shrinking and she has maintained quality of life.

Patient

Male, early 60’s

Diagnosis

Lung cancer

A man in his early 60’s from a major city was diagnosed with lung cancer, despite never having smoked. He had multiple types of chemotherapy and radiotherapy over almost 10 years. The gentleman was then referred to the MoST Program, which found a very rare gene expression change. As a result, he was eligible for a MoST-sponsored substudy. He is still on treatment, over one year later and is doing very well.

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

Patient

Male, early 70’s

Diagnosis

Lung cancer

A man in his early 70’s from regional Victoria had a history of melanoma. He then developed another cancer – thought to start in his lungs. He was referred to the ASPiRATION program, and the lung tumour sequencing results revealed that the “lung” tumour was actually a metastasis (or spreading) of the melanoma that had been surgically removed more than five years ago. As a result, his treatment changed, and his cancer has shrunk. He has a better quality of life now than when originally referred to the program a year ago.

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

Translational Oncology Laboratory (TOL)

The Translational Oncology Lab (TOL) conducts in depth molecular and biological analysis of patient samples collected on the Molecular and Screening Therapeutics (MoST) program clinical trials to identify prognostic and retrospective biomarkers of response to drugs.

Dynamic changes in circuiting tumour DNA (ctDNA) predict durable responses to immune checkpoint inhibitors (ICI).:

Despite the clinical potential of ICI treatment to improve patient survival, to date, only a minority of patients gain long-term benefits. There is an urgent need to identify biomarkers of early response that can accurately predict the benefit to patients of ICI. Radiographs are one way of monitoring disease response - complete response (CR) partial response (PR), stable disease (SD), or progressive disease (PD). RECIST criteria are used to characterise tumours. However, patients receiving immunotherapy can be difficult to evaluate using RECIST due to the possibility of pseudoprogression which can be seen in images. Monitoring circulating tumour DNA (ctDNA) is emerging as a potential personalized biomarker that can be measured longitudinally and might predict survival outcomes in patients earlier in the treatment journey.

The durvalumab and tremelimumab (MoST 2) trial has investigated the response of 112 patients with advanced cancers, to the dual immune checkpoint inhibitor treatent. Assessment of ctDNA was conducted in collaboration with Roche to determine if dynamic changes early in treatment could predict clinical benefit from ICI's. ctDNA is released by tumour cells into the bloodstream and thus carries the genetic changes of the original tumour.

A subset of patients, representing 16 solid tumour histologies, had their tumour samples DNA panel sequenced before treatment to identify genomic alterations in the tumour. This information was used to develop personalised assays. ctDNA load in blood samples was measured at baseline and 4 and/or 8 weeks into treatment. Changes in ctDNA were correlated with radiographic response and overall survival (OS).

A decline in ctDNA from baseline as early as 4 weeks into treatment predicted improved OS (P=0.0144; HR 9.88) and ctDNA changes on treatment-supported and improved radiographic response calls. Early ctDNA clearance at any time through to week 8 identified patients that were complete responders ahead of radiographic imaging by a median lead time of 11.5 months. The clearance of ctDNA in blood identified patients with a highly favourable outcome (Fig 1A). Fig B shows two patients who had ctDNA clearance followed by a CR (Fig 1B). These findings were published in Molecular Oncology (Dec 2022). Further work investigating the use of ctDNA in monitoring and predicting response to ICI as well as other targeted therapy is underway.

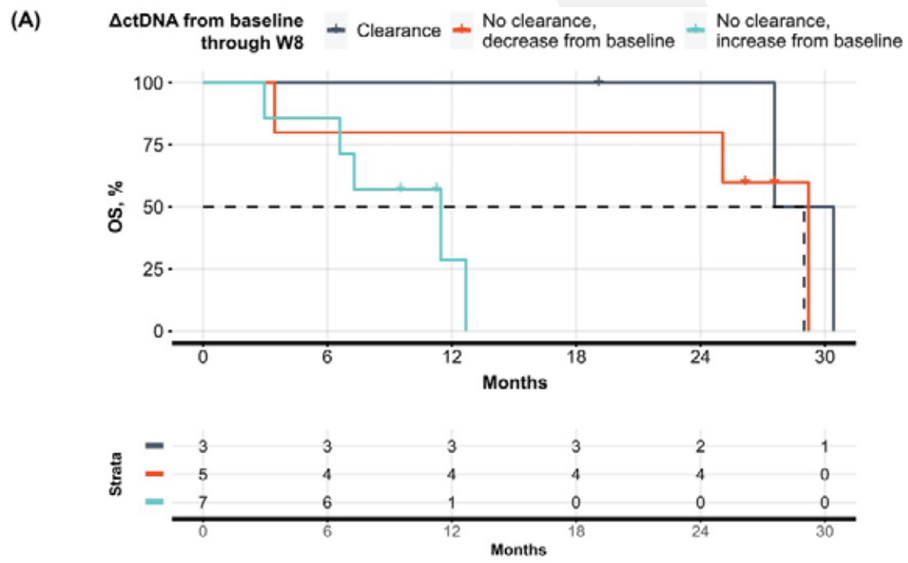
Testing protein biomarkers that may indicate new opportunities for patients in the MoST program.

Protein biomarkers are molecules present in abnormal amounts or having abnormal function in cancer cells. They can be used to detect the presence of cancer, determine the stage of the disease, and monitor treatment response. In oncology clinical trials, protein biomarkers can be used to identify patients most likely to benefit from a specific treatment, known as biomarker-driven clinical trials.

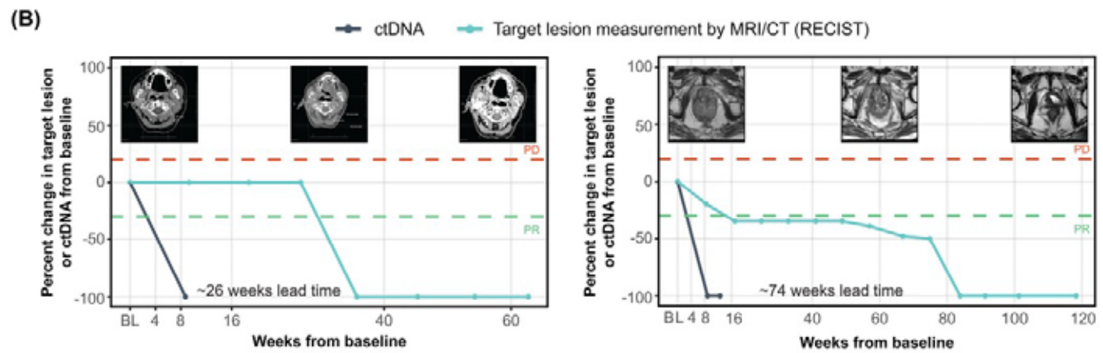
Antibody-drug conjugates (ADCs) are a type of cancer treatment that combines the specificity of antibodies targeting particular proteins with cytotoxic agents, for example, chemotherapy delivering a toxic payload to specific cancer cells. The use of protein biomarkers is crucial in the development and use of ADCs. As of 2023 there are more than 20 ADCs approved for the treatment of various cancers.

Colorectal cancer (CRC) is one of the most common human malignant diseases worldwide. The MoST program has screened >600 patients with CRC. Metastasis is the leading cause of CRC treatment failure and death.

A promising ADC, sacituzumab govitecan (Trodelvy's), has shown efficacy in patients expressing the protein biomarker Trophoblast antigen Protein 2 (TROP-2). TROP-2 is a protein expressed in several epithelial cancers, including oral, lung, pancreatic, and gastric carcinoma. Functionally, TROP-2 is involved in the regulation of carcinoma cell growth and activation of the signaling pathways involved in tumour invasiveness and metastasis. TROP-2 protein is expressed at high levels and is associated with the development and



ΔctDNA from baseline through W8	1-year survival	*P* value	Median OS (months)	HR (95% CI)	*P* value
Clearance	100% (3/3)	Ref	29.0	Ref	Ref
No clearance, decrease from baseline	80% (4/5)	1.0	29.21	2.37 (0.24-23.16)	0.46
No clearance, increase from baseline	14% (1/7)	0.03	11.47	20.88 (1.21-357.90)	0.04



Change from BL	W4	W8	W16	W34
ctDNA	-	Clearance	-	-
RECIST	-	SD	SD	CR

Change from BL	W4	W8	W16	W82
ctDNA	Clearance	Clearance	-	-
RECIST	-	SD	PR	CR

Figure 1. Ct DNA clearance identifies patients with longer overall survival (OS).

(A) Kaplan Meier Curve of OS stratified by change in ctDNA from baseline to week 8.

(B) Two patients had ctDNA clearance followed by an CR by RECIST criteria.

pathological progression of CRC.

In a pilot study, we assessed patients with advanced CRC and lung metastasis to determine TROP-2 expression by immunohistochemistry (IHC).

IHC scores were graded from 0 to 3 and a grade ≥2 was considered to be positive. Interpretation of TROP-2 staining was carried out by a qualified pathologist. The human tonsil was used as a positive control.

The percentage of tumour cells with membranous TROP-2 immunoreactivity was estimated and the staining intensity assessed semi-quantitatively as follows: 0, no staining; 1+, weak; 2+, moderate and 3+, strong staining.

The final immunoreactivity score was calculated by multiplying staining intensity (1+, 2+, 3+) with the percentage of positive tumour cells, and then classified into 4 ordinal categories:

- 0–9 negative (score 0),
- 10–99 weak (score 1),
- 100–199 moderate (score 2), and
- 200–300 strong (score 3).

Table 1 shows scores for the pilot study investigating TROP expression. Figure 2 shows an example of strong TROP2 staining in colorectal cancer liver metastasis.

As new drugs develop, there is a need to investigate protein expression in tumour types that may have been overlooked, particularly in rare cancers, to determine the potential for response.

We are currently building capacity for multiplexing IHC staining to identify new indications for new and upcoming ADCs as well as drugs targeting the immune system and other targeted therapies.

	IHC score						
Case	0	1+	2+	3+	Overall score	Category	Comment
1	100	0	0	0	0	negative (0)	non-specific staining only
2	20	10	20	50	200	strong (3)	good internal control (bile ducts)
3	0	10	50	40	230	strong (3)	tumour shows gradient effect ? Related to fixation
4	90	5	0	0	5	negative (0)	some focal cytoplasmic staining (10%)
5	100	0	0	0	0	negative (0)	good internal control (bile ducts)
6	80	5	5	10	45	weak (1)	some focal cytoplasmic staining (20%)
7	80	10	10	0	30	weak (1)	mostly cytoplasmic staining (40%)
8	0	0	0	100	300	strong (3)	minute focus of tumour at one end of one liver core (<50 cells)
9	80	0	10	10	30	weak (1)	Only periphery of tumour staining
10	90	10	0	0	10	weak (1)	mostly cytoplasmic staining (40%)
Control	0	0	0	100	300	strong (3)	weak cytoplasmic staining in germinal centre

Table 1. Immunohistochemistry (IHC) scores for a pilot study investigating TROP2 expression in colorectal cancer liver metastasis. Liver metastatic tumour specimens were probed for TROP-2 monoclonal antibody, Enzo (ENZ-ABS380). Interpretation of TROP-2 staining was carried out by a qualified pathologist.

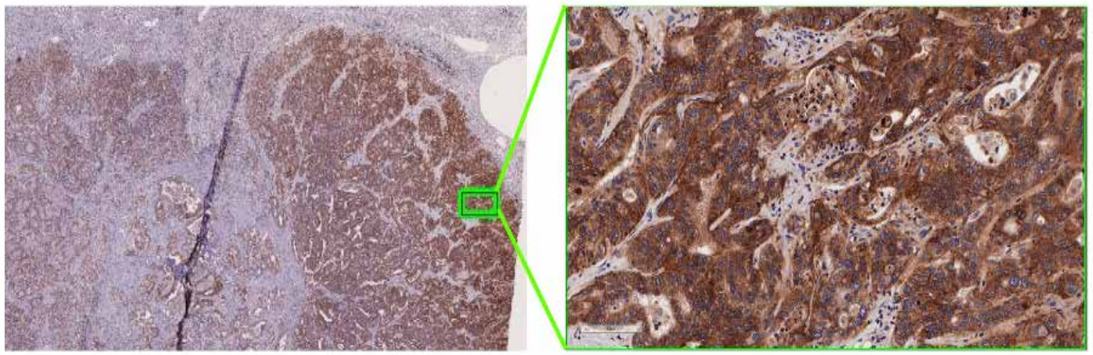


Figure 2. IHC example of strong TROP2 staining in a colorectal adenocarcinoma that's metastasized to liver (brown staining shows TROP2 protein expression.

Genomic clues and protein validation, biomarkers that may indicate new opportunities for patients in the MoST program.

Protein biomarkers are molecules that are present in abnormal amounts or have abnormal functions in cancer cells. They can be used to detect the presence of cancer, determine the stage of disease or monitor treatment response. In cancer clinical trials, protein biomarkers can be used to identify patients who are most likely to benefit from a specific treatment. These are known as biomarker-driven trials.

Immune checkpoint inhibitors (ICI), for example, programmed cell death-1 ligand or receptor (PD-L1/PD-1), have revolutionised the treatment of many solid cancer tumours. However, ICI has only had the desired effect in a subset of patients. Biomarkers for determining response to ICI targeting PD-L1/PD-1 include PD-L1 protein expression, high tumour mutation burden (TMB), and microsatellite instability (MSI). In Non-Small Cell Lung cancer (NSCLC), amplification of the CD274 gene that encodes PD-L1, is a potential biomarker that identifies a molecular subgroup that might respond to ICI.

We are currently investigating the relationship between CD274 amplification and PD-L1 expression in the MoST cohort. To date, we have identified 18/6629 (0.27%) patients whom have CD274 gene amplification, 16 of who have co-amplification of PDCD1LG2, and 12 with JAK2 amplified. Of the 18 patients with CD274 amplified, 11 have rare or less common cancers.

Figure 3 shows 3 sarcoma patients who had CD274 gene amplification detected in genomic panel screening. Investigation using IHC staining found high PD-L1 expression (A & B 80%, C& D 90%, and E & F 70%) in all three tumours, suggesting these patients may be good candidates for treatment with anti-PD1/PDL1 targeted drugs. Rare cancers are not usually screened for PD-L1 expression and this may open new treatment opportunities for this patient population. These studies are ongoing.

Correlative studies investigating biospecimens from MoST 10 - Palbociclib + Avelumab and Most 11 tildrakizumab are ongoing.

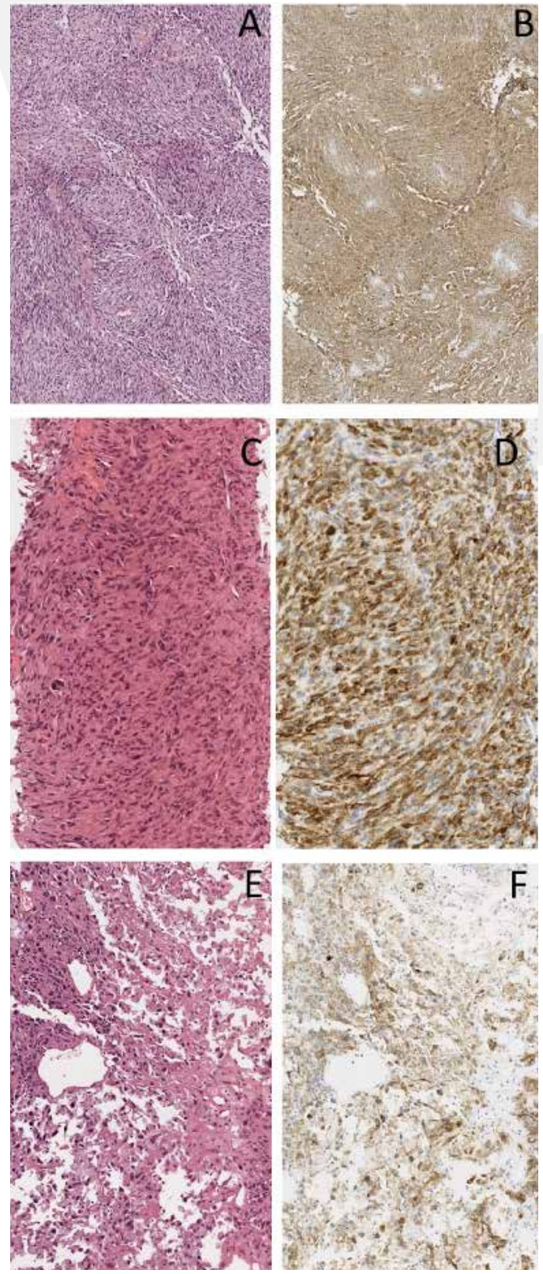
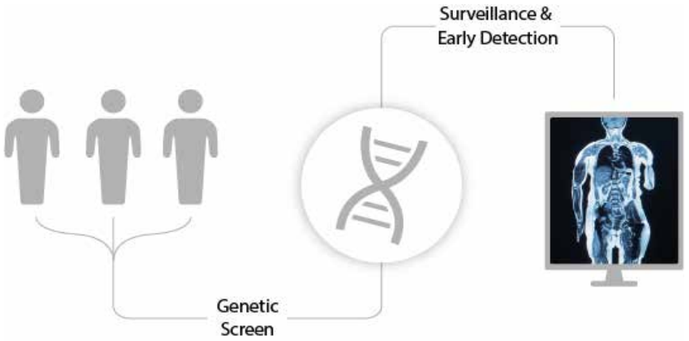


Figure 3: IHC investigating PD-L1 expression in patients with soft tissue sarcomas identified by CD274 amplification. A & B (angiosarcoma), C & D and E & F are consecutive slides from the sample patient, H&E staining on the left showing tumour morphology, PD-L1 staining (SP273) shown in brown on the right. Quantitation of staining was carried out by a qualified pathologist.

Genetic Cancer Risk in the Young (RisC) study

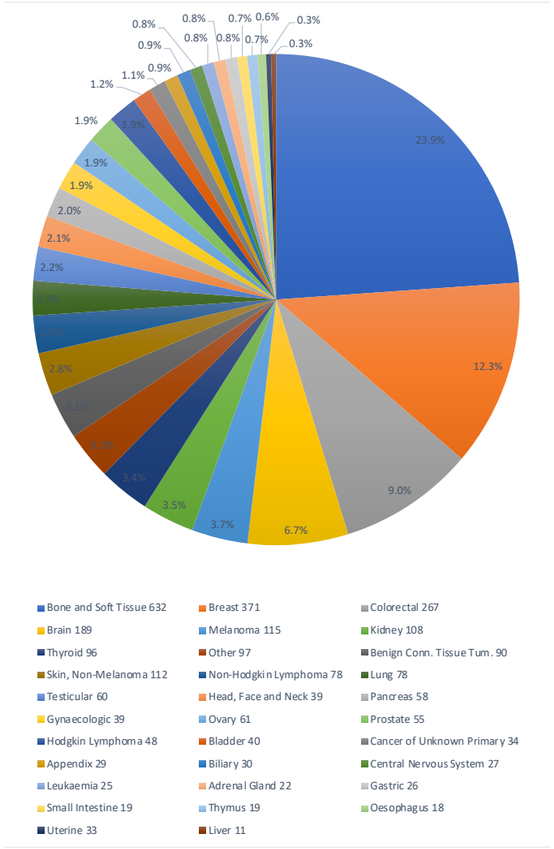


Early onset cancers represent a significant burden of cost, morbidity and mortality to the community. Evidence suggests that cancer in the young is largely driven by heritable causes and there is a higher risk of developing a second cancer as well as implications for family members.

The RisC study is a cancer cohort study investigating the heritability of cancer in young people using the power of whole genome sequencing. The RisC study hypothesizes that a diagnosis of cancer at an early age or multiple cancer diagnoses over a lifetime are good indicators that heritable factors are at play. The RisC study enrols individuals who have been diagnosed with cancer under the age of 40 years and also those who have had multiple different cancers. Study participants donate a blood sample and provide clinical, demographic and epidemiological data as well as information about the family history of cancer.

Understanding heritable cancer risk is important as it allows individuals at high cancer risk to be identified and clinical risk management strategies to be implemented. Increasingly this information also has therapeutic implications and can inform lifestyle and reproductive decisions.

Those 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+).

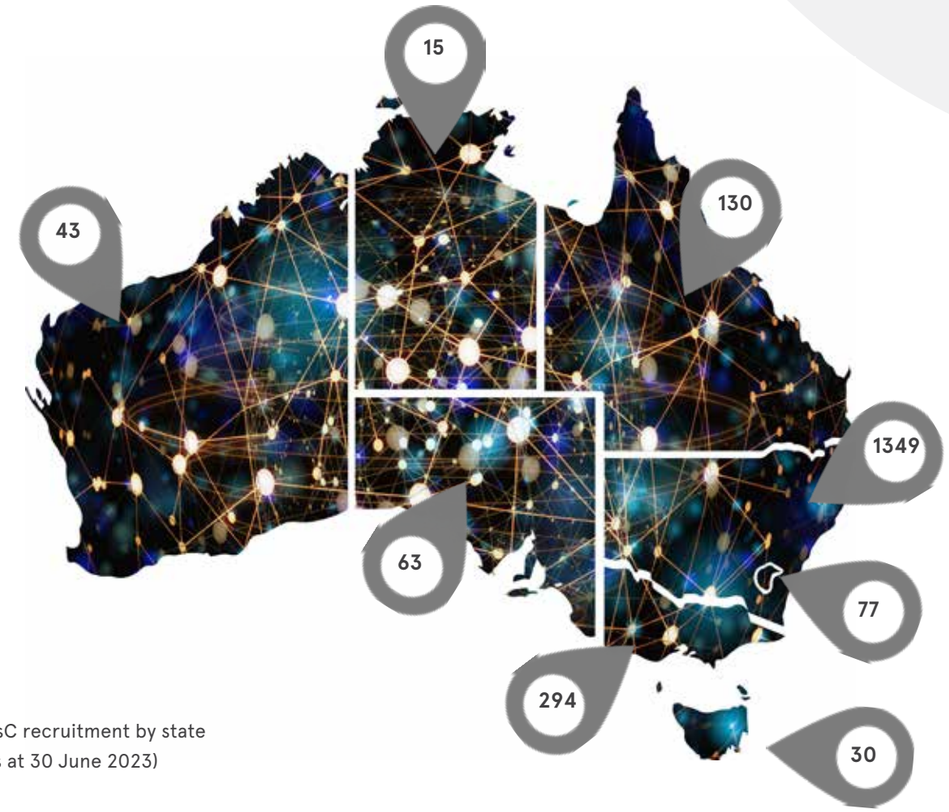


The different cancer types identified in RisC patients

By the end of September 2023:

- 2092 probands have been enrolled from around the country
- · 453 family members have agreed to participate
- · RisC probands are 59% female and 24% have had multiple primary cancers.
- · Germline whole genome sequencing has been completed on 1570 probands
- · The most common cancer types in the cohort are bone and soft tissue sarcomas, breast cancer, colorectal cancer and brain tumours. Almost 60% of the RisC cancers are classified as rare (<6/100,000 populBy the end of September 2023:

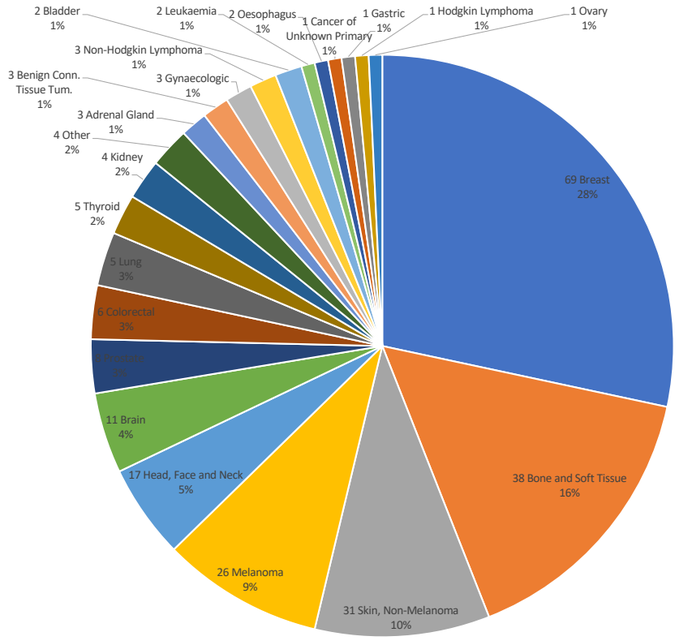
* a proband is a person serving as the starting point for the genetic study of a family



RisC recruitment by state
(as at 30 June 2023)

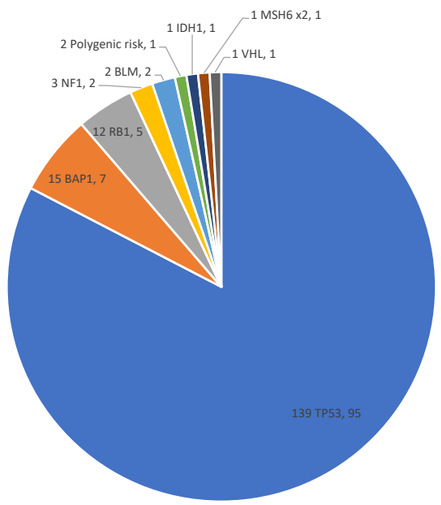
Surveillance in Multi-Organ Cancers (SMOC+) study

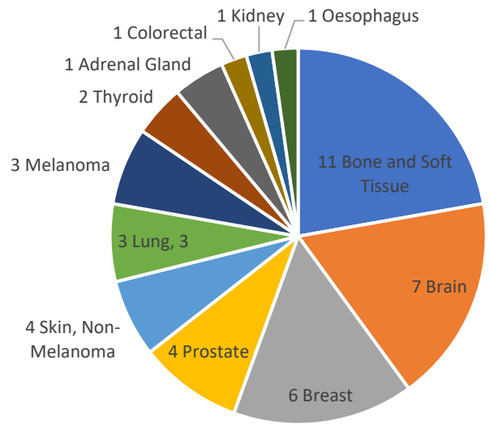
- One hundred and eighty-seven (187) patients have been enrolled in the SMOC+ study Australia wide with 111 from Victoria, 68 from NSW and 8 from South Australia.
- Participants 64% female and just under 80% have germline pathogenic variants in the TP53 gene (Li Fraumeni syndrome).
- Forty-four (44) new primary cancers have been detected in 31 individuals as a result of participation in the study.
- The SMOC Junior study investigating whole body MRI surveillance in children at high cancer risk started recruitment in November 2022.
- A Medicare item number for annual whole body MRI surveillance for Li Fraumeni syndrome has been issued.
- The SMOC+ Study is currently recruiting in New South Wales, Victoria and South Australia.
- SMOC+ has addressed an unmet clinical need for surveillance in cancer-prone individuals, which is highlighted by the continued recruitment to the study.



The range of cancer diagnosed in SMOC+ Study patients. Cancers of the breast and bone and soft tissue account for 44% 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)

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





SMOC+ Study surveillance led to 44 cancer diagnoses in 31 patients.

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
- ~200 indirect jobs created.

2023 :

Omico landmark initiative PrOSPeCT

- >20 private and public sector entities involved
- Reaching more than 23,000 Australians with advanced cancer
- Leveraging more than $185M of federal and private sector funding
- Grow the largest precision cancer medicine network created in this country: PrOSPeCT.

Cancer

meets its match

Advocacy and support

Rare Cancers Australia (RCA)

Patient Support Program

The RCA Patient Care Team has a staff of 4 FTE and is currently providing support via direct contact (verbal or written) to 1,100 patients with either rare or less common cancers.

In the period 1 July, 2022 to 31 June 2023 RCA has provided verbal or written support to 590 new patients. Of these, 120 patients have been provided information about and referred to the OMICO Program (MoST).

ARC Portal – RCA has referred 75 patients to the ARC portal in the 12 month period.

Rare Cancer Support Guide

In November 2022 RCA Launched the Rare Cancer Support Guide which provides a comprehensive set of information specifically designed for patients. Copies have now been distributed to major cancer centres across Australia. The guide includes detailed descriptions of the MoST trial and the ARC Portal.

Centre Visits

Following the lifting of COVID restrictions RCA is progressively engaging with major cancer centres we are now actively working with 40 hospitals and cancer centres. As part of our awareness program RCA maintained an information kiosk at Cancer Nurses Society Conference and at the annual COSA Conference. We have also attend and spoken at the Private Cancer Physicians Conference and a number of other conferences relevant to our work

Web & Social Media presence

RCA has continued to maintain a strong social media and web presence and this continues to expand. Refer to the appendix for more detail.

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 other emerging treatments.

Patient Advisory Board

Our PAB continues to function and providing constant and valuable input to RCA's work in patient support. The Advisory Board is proving of high value in shaping the report released at Canforum 2023 based around a study and explanation of the development of genomic science and the consequences for cancer care.

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 twelve 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 continues to provide briefings to the Federal Government on the health, social and economic benefits of the expanded Omico program.

Rare Cancers Awareness Month

As part of RCA's ongoing awareness raising activity, we held the second Rare Cancers Awareness Day on June 26, 2023. The event was primarily a social media campaign and it reached over 4 million viewers with 25 patient organisations, 20 corporate organisations and 51 patient advocates joining in spreading awareness for rare cancers. RCA is currently planning a bigger event in 2024.

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.

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 a global event hosted by the HTA i

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.

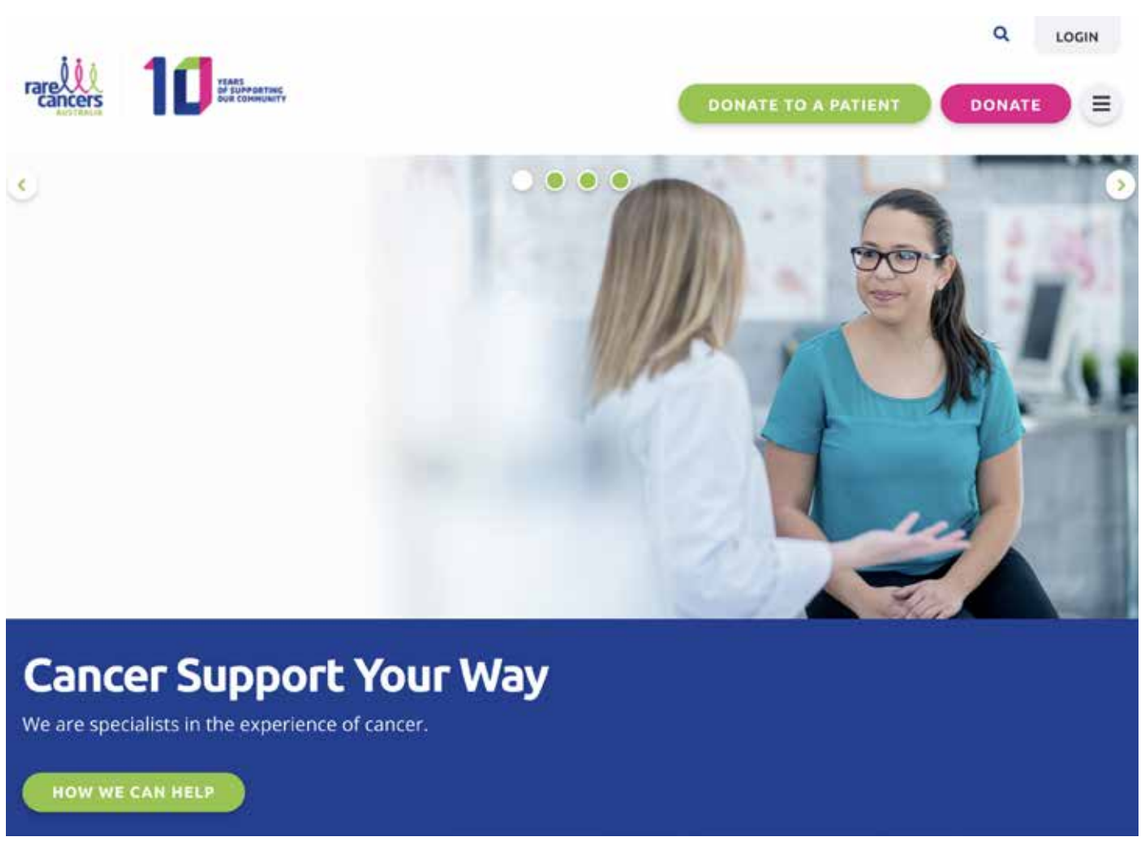
Communications

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 continue as part of the Omico Program, and we are pleased with our progress during this past twelve months. We look forward to continuing our substantial support and contribution over the coming years of the project.

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



Rare Cancer Portal

AUSTRALIAN RARE CANCER PORTAL

Key achievements to 30 June 2023:

ARC Portal website and online referral service – www.arcportal.org.au.

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

At the time of reporting the ARC Portal has **over 275 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 1400 individual patients with rare cancers registered

The ARC Portal has been referred 1463 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 (27%) or relapsed/progressing disease (46.3%), with the remainder stable (16.4%) or in remission (9.8%).

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 (84.7%) or other biospecimens (84.1%), 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 425 samples which have been referred for Whole Genome Sequencing or Whole Exome Sequencing (depending on fresh vs FFPE tissue or tumour purity available), with highly actionable findings identified in over half (67%) of the whole genome sequencing reports analysed to date.

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

An analysis of patient referrals coded by Australian Statistical Standard Remoteness Structure demonstrated that 45% of ARC Portal referrals were from outside major cities (major cities, 55%; inner regional, 34%; outer regional, 8%; remote or very remote, 3%). This is out of proportion to the population living in these regions (major cities, 71% vs other, 29%; ABS data 2016) and helps demonstrate the need the ARC Portal addresses in providing patients living outside of major cities access to the same rare cancer expertise, molecular testing, trials and other research opportunities, often only available to patients treated at tertiary or specialist cancer centres.

Achievements in the last 6 months:

Triaging and assisting patients - 3 current fellows (1.0 EFT total). 2 new fellows onboarded (NSW) and 1 ongoing (VIC). Contract near completion for QLD based fellow for 2023 Q3-4 (funded by philanthropy).

Reviewing year 4 activity - Analysis of first 1000 referrals and psychosocial patient impact analysis presented at COSA 2022 and ASCO 2022, respectively. Patients' satisfaction of handling will not be measured as patient feedback is not being actively solicited.

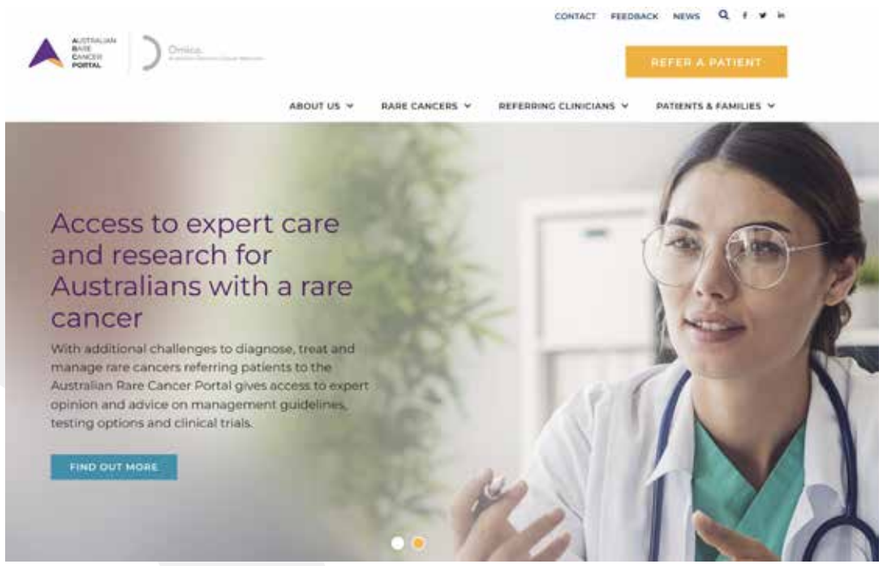
Data integration, data management and reporting for Portal by BioGrid -Patient impact and resource measurement instruments being updated for 2023. Ongoing usability refinements to the Portal database and processes API's for data integration across rare cancer databases in development.

Comparison of outcomes Year 4 vs Years 1-3 - Ongoing cross-referral between RCA and ARC Portal; regular meetings to triage patient referrals; development of standardized pathways for individual patient fundraising; drug access programs; patient support.

Plan for patient referrals and service implementation

Portal referral activity through 2022 into 2023 remains steady following initial slower accrual in the context of the COVID pandemic restrictions. Our 2023 fellows are based geographically in Victoria and NSW, with involvement of clinicians based in the Sunshine Coast University Hospital anticipated for 2023 Q3-4. An analysis of patient referrals in 2022, demonstrated that a disproportionately high 45% were from outside of major cities reflecting the need for improved access to specialist rare cancer services in these regions. In 2023 there has been ongoing growth in the number of referring clinicians, with many clinicians referring multiple patients reflecting a growing and satisfied referrer base. Feedback has been extremely positive about the assistance we have provided.

Strategic meetings with colleagues in health service implementation and health economics are underway toward an implementation project to address the long-term sustainability of the ARC Portal program.



Research outputs

Publications (120 to 30 September 2023)

2022

1. Best M, Bartley N, Napier CE, Fisher A, Ballinger ML, Thomas DM, Goldstein D, Tucker KM, Biesecker B, Butow P. 2022 Return of comprehensive tumour genomic profiling results to advanced cancer patients: a qualitative study. Support Care Cancer 30, 8201–8210 (2022). https://doi.org/10.1007/s00520-022-07272-3

2. Best M, Napier C, Schlub T, Bartley N, Biesecker B, Ballinger M, Butow P. Validation of the multidimensional impact of Cancer Risk Assessment Questionnaire to assess impact of waiting for genome sequencing results. Psychooncology. 2022 Jul;31(7):1204-1211. doi: 10.1002/pon.5908. Epub 2022 Mar 1. PMID: 35194887.

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4. Butow P, Bartley N, Napier C, Best M, Campbell R, Ballinger ML. Validation of the Knowledge of Genome Sequencing (KOGS) scale in cancer patients. Accepted by the Patient Education and Counseling journal on 14 June 2022

5. Butow P, Best MC, Davies G, Schlub T, Napier CE, N Bartley N, et al., Psychological impact of comprehensive tumor genomic profiling results for advanced cancer patients. Patient Educ Couns. 2022 Jan 24:S0738-3991(22)00034-9. doi: 10.1016/j.pec.2022.01.011. Epub ahead of print. PMID: 35153126.

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10. Krebs, M. G., U. Malapelle, F. André, L. Paz-Ares, M. Schuler, D. M. Thomas, G. Vainer, T. Yoshino, and C. Rolfo. 2022 Practical Considerations for the Use of Circulating Tumor DNA in the Treatment of Patients With Cancer: A Narrative Review. JAMA Oncology 8(12):1830–1839. doi:10.1001/jamaoncol.2022.4457

11. Lacaze PA, Tiller J, Winship I, DNA Screen Investigator Group, Lacaze P, Tiller J, Winship I, Brotchie A, McNeil J, Zalcberg J, David Thomas D, et al., Population DNA screening for medically actionable disease risk in adults. Medical Journal of Australia 216 (6), 278-280

12. Lau LMS, Mayoh C, Xie J, Barahona P, MacKenzie KL, Wong M, Kamili A, Tsoli M, Failes TW, Kumar A, Mould EVA, Gifford A, Chow SO, Pinese M, Fletcher JI, Arndt GM, Khuong-Quang DA, Wadham C, Batey D, Eden G, Trebilcock P, Joshi S, Alfred S, Gopalakrishnan A, Khan A, Grebert Wade D, Strong PA, Manouvrier E, Morgan LT, Span M, Lim JY, Cadiz R, Ung C, Thomas DM, Tucker KM, Warby M, McCowage GB, Dalla-Pozza L, Byrne JA, Saletta F, Fellowes A, Fox SB, Norris MD, Tyrrell V, Trahair TN, Lock RB, Cowley MJ,

Ekert PG, Haber M, Ziegler DS, Marshall GM. In vitro and in vivo drug screens of tumor cells identify novel therapies for high-risk child cancer. EMBO Mol Med. 2022 Apr 7;14(4):e14608. doi: 10.15252/emmm.202114608. Epub 2021 Dec 20. PMID: 34927798; PMCID: PMC8988207.

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14. Meiser B, Butow P, Davies G, Napier CE, Schlub TE, Bartley N, Juraskova I, Ballinger ML, Thomas DM, Best MC, Psychological predictors of cancer patients' and their relatives' attitudes towards the return of genomic sequencing results. European Journal of Medical Genetics 65 (6), 104516

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19. Thavaneswaran S, Lin FP, Kansara M, Grady JP, Espinoza D, Joshua AM, Grimison P, Craft P , Cosman R, Lee C, Harwood K, Chinchen S, Corpuz T, Ballinger M, Sebastian L, Simes J, Thomas D. A signal-seeking Phase II trial of Durvalumab and Tremelimumab Focused on Advanced, Rare and Less Common Cancers. medrxiv 2022. doi: https://doi.org/10.1101/2022.06.30.22277092

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2023

1. Kansara, M., Bhardwaj, N., Thavaneswaran, S., Xu, C., Lee, J. K., Chang, L. B., ... & Thomas, D. M. (2023). Early circulating tumor DNA dynamics as a pan-tumor biomarker for long-term clinical outcome in patients treated with durvalumab and tremelimumab. Molecular Oncology, 17(2), 298-311.

2. Ballinger, M. L., Pattnaik, S., Mundra, P. A., Zaheed, M., Rath, E., Priestley, P., ... & Nicolas, G. (2023). Heritable defects in telomere and mitotic function selectively predispose to sarcomas. Science, 379(6629), 253-260.

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4. Lu, C. Y., Terry, V., & Thomas, D. M. (2023). Precision medicine: affording the successes of science. NPJ Precision Oncology, 7(1), 3.

5. Harrison C, Bartley N, Jacobs C, Best M, Vatter S, Meiser B, Ballinger ML, Thomas DM, Butow P; members of the PiGeOn Project. Family communication and results disclosure after germline sequencing: A mixed methods study. Patient Educ Couns. 2023 May 19;114:107800. doi: 10.1016/j.pec.2023.107800. Epub ahead of print. PMID: 37210765.

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7. Thavaneswaran, S., Kansara, M., Lin, F. et al. A signal-seeking Phase 2 study of olaparib and durvalumab in advanced solid cancers with homologous recombination repair gene alterations. Br J Cancer 1-11 (2023). https://doi.org/10.1038/s41416-023-02311-0

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9. Stacchiotti S, Maria Frezza A, Demetri GD, Blay JY, Bajpai J, Baldi GG, ...Thomas DM, ... Retrospective observational studies in ultra-rare sarcomas: A consensus paper from the Connective Tissue Oncology Society (CTOS) community of experts on the minimum requirements for the evaluation of activity of systemic treatments. Cancer Treat Rev. 2022 Nov;110:102455. doi: 10.1016/j.ctrv.2022.102455. Epub 2022 Aug 18. PMID: 36031697.

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11. Mersiades AJ, Solomon BJ, Thomas DM, Lee CK, Cummins MM, Sebastian L, Ballinger ML, Collignon E, Turnbull OM, Yip S, Morton RL, Brown C, Wheeler PJ, Itchins M, Simes RJ, Pavlakis N. ASPiRATION: Australian observational cohort study of comprehensive genomic profiling in metastatic lung cancer tissue. Future Oncol. 2023 Sep 28. doi: 10.2217/fon-2023-0366. Epub ahead of print. PMID: 37767626.

12. Sabesan S, Malica M, Gebbie C, Scott C, Thomas D, Zalcberg J. Implementation of the Australasian Teletrial Model: Translating ideas into action using implementation science frameworks. J Telemed Telecare. 2023 Sep;29(8):641-647. doi: 10.1177/1357633X211017805. Epub 2021 Jul 7. PMID: 34233548.

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Presentations &Abstracts

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 (ASCO International conference abstract).

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 abstract).

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.

8. R. Sharaf, D.X. Jin, J. Grady, G.M. Frampton, L.A. Albacker, D. Thomas, M. Montesion.1487MO A pan-sarcoma investigation of genetic alterations associated with high telomeric content, Annals of Oncology, Volume 33, Supplement 7, 2022, Pages S1226-S1227

9. D Serie, C Pickering, R Rice, M Wong, H Huang, M Kansara, S Thavaneswaran, M Ballinger, L Sebastian, DM Thomas, and K Lindpaintner 2022 Serum glycoproteomic signatures and association with survival in patients with bone and soft tissue sarcoma treated with immune-checkpoint inhibitor therapy. Journal of Clinical Oncology 40:16_suppl, 11546-11546.

10. S Thavaneswaran, F Lin, J Grady, C Napier, M Kansara, M Ballinger, K Sjoquist, D Goldstein, J Simes and D Thomas. Genomic targetability of cholangiocarcinomas and outcomes for Australian patients screened through the Molecular Screening and Therapeutics (MoST) program. Best of Best oral presentation, AGITG ASM. 2022

11. S Thavaneswaran The Genomic Landscape of Brain cancers – the MoST experience – Invited speaker at the COGNO Annual Scientific Meeting. October 2022.

12. S Thavaneswaran Treatment based on Genomic profile – Invited speaker at the General Surgeons Australia Annual Scientific meeting. October 2022.

13. Pitiyarachchi, O., Sharbeen, G.S., Lin, E., Lin, F., Neal, B., Di Tanna, G.L., Ballinger, M.L., Singhal, N., Collignon, E., Sjoquist, K.M., Chantrill, L.A., Thomas, D., Goldstein, D., Phillips, P.A.. SPEAR: A Phase 2, Open-label, Single-arm Monotherapy Trial of Sulfasalazine in Patients with Pancreatic Adenocarcinoma – Trial in Progress. Presented at Australasian Gastrointestinal Trials Group. Annual Scientific Meeting, Melbourne, 14-17 Nov 2022

2023

1. Genomic targetability and survival outcomes of biliary tract cancers (BTC): A retrospective cohort study of the Australian Molecular Screening and Therapeutics (MoST) program. S Thavaneswaran, FPY Lin, CE Napier, JP Grady, ML Ballinger, ...Journal of Clinical Oncology 41 (16_suppl), 4093-4093

2. Long-term clinical and psychosocial outcomes of surveillance in Li Fraumeni syndrome. M Zaheed, CE Napier, EJ Cops, N Ferris, K Moodie, B Milner, D Moses, ...Journal of Clinical Oncology 41 (16_suppl), 10578-10578

3. Molecular tumor profiling and therapy selection in advanced gynecological cancers: A retrospective cohort analysis from the Australian Molecular Screening and Therapeutics ...D Kee, FPY Lin, S Thavaneswaran, CE Napier, ML Harrison, PJ Beale, ...Journal of Clinical Oncology 41 (16_suppl), 5526-5526

4. Clinical activity of palbociclib and ribociclib monotherapy in advanced cancers with cyclin D-CDK4/6 pathway alterations in the Dutch DRUP and Australian MoST trials.LJ Zeverijn, E Looze, S Thavaneswaran, JM van Berge Henegouwen, ...Journal of Clinical Oncology 41 (16_suppl), 3101-3101

5. Genomic alterations associated with response to immune checkpoint inhibitors in rare cancers: A biomarker exploration study from the Australian Molecular Screening and ...M Kansara, FPY Lin, S Thavaneswaran, CE Napier, JP Grady, ...Journal of Clinical Oncology 41 (16_suppl), 2594-2594

6. Genomic therapy matching in rare and refractory cancers: Updated results from a retrospective cohort study in the Molecular Screening and Therapeutic (MoST) program. FPY Lin, S Thavaneswaran, CE Napier, JP Grady, M Kansara, ...Journal of Clinical Oncology 41 (16_suppl), 1540-1540

7. Trastuzumab emtansine (T-DM1) in advanced cancers with HER2 mutations or amplification: Results from the Molecular Screening and Therapeutics (MoST) Program substudy. S Thavaneswaran, A Mersiades, FPY Lin, D Espinoza, JP Grady, CK Lee, ...Journal of Clinical Oncology 41 (16_suppl), 3127-3127

Australian Genomic Cancer Medicine Centre Limited

ABN 67 627 640 733

Financial Report

For the year ended 30 June 2023

Contents

Corporate Information Statement

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

ABN 67 627 640 733

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

Mr Paul Jeans (Chair)
Mr Richard Vines (Deputy Chair)
Professor Michael Brown
Professor Ricky Johnstone
Professor Susan MacLeman
Ms Tze Masters
Professor Robert Simes
Professor Benjamin Kile
Professor David Thomas

Company Secretary
Associate Professor Paul Martin

Chief Executive Officer
Professor David Thomas

Address
University of NSW
L6 Hilmer Building (E10), Union Road
Kensington NSW 2052
Australia

Auditor
Grant Thornton

Statement of profit or loss and other comprehensive income

For the year ended 30 June 2023

	Note	2023 $	2022 $
Revenue from operations	2	24,469,469	16,392,090
Interest income		801,318	86,368
Total revenue and other income		**25,270,787**	**16,478,458**
Service provider and project expenses	3	(14,710,879)	(12,584,110)
Consulting and support services expenses	4	(1,344,338)	(654,742)
Employee costs		(479,693)	(243,788)
Research materials		(276,209)	(1,001,437)
Other administrative costs		(1,648,173)	(229,915)
Total costs		**(18,459,292)**	**(14,713,992)**
Surplus for the year		**6,811,495**	**1,764,466**
Other comprehensive income		**-**	**-**
Total comprehensive income for the year		**6,811,495**	**1,764,466**

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

Statement of financial position

As at 30 June 2023

	Note	2023 $	2022 $
Assets			
Current assets			
Cash and cash equivalents	5	61,600,309	20,349,099
Trade and other receivables	6	1,108,132	406,233
Other assets	7	1,511,856	35,315
Total current assets		**64,220,297**	**20,790,647**
Non-Current assets			
Property, plant and equipment	8	9,038	887
Total non-current assets		**9,038**	**887**
Total Assets		**64,229,335**	**20,791,534**
Liabilities			
Current liabilities			
Contract liability	9	35,809,568	3,435,507
Trade and other payables	10	6,017,622	1,777,317
Provisions	11	69,631	57,691
Total current liabilities		**41,896,821**	**5,270,515**
Total liabilities		**41,896,821**	**5,270,515**
Net assets		**22,332,514**	**15,521,019**
Funds			
Accumulated surplus	12	22,332,514	15,521,019
Total funds		**22,332,514**	**15,521,019**

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

Statement of changes in funds

For the year ended 30 June 2023

	Accumulated Funds $	Total Funds $
Balance at 1 July 2021	13,756,553	13,756,553
Surplus for the year	1,764,466	1,764,466
Other comprehensive income for the year	-	-
Balance at 1 July 2022	**15,521,019**	**15,521,019**
Surplus for the year	6,811,495	6,811,495
Other comprehensive income for the year	-	-
Balance at 30 June 2023	**22,332,514**	**22,332,514**

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

Statement of cash flows

For the year ended 30 June 2023

	Note	2023 $	2022 $
Cash flows from operating activities			
Receipts from government grants, other funding and other revenue		56,534,537	16,766,174
Payments to funding recipients, suppliers and employees		(16,075,607)	(16,939,006)
Interest received		801,318	86,368
Net cash flows from operating activities	13	**41,260,248**	**(86,464)**
Cash flows from investing activities			
Acquisition of plant and equipment		(9,038)	-
Net cash flows from investing activities		**(9,038)**	**-**
Net change in cash and cash equivalent		41,251,210	(86,464)
Cash and cash equivalents at beginning of year		20,349,098	20,435,562
Cash and cash equivalents at end of year	5	**61,600,309**	**20,349,098**

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

Notes to the financial statements

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

These general-purpose financial statements have been prepared in accordance with the requirements of the *Australian Charities and Not-for-profits Commission Act 2012*, Australian Accounting Standards – 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 30 August 2023.

1. Significant accounting policies

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

(a) Revenue

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

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

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

1. Identify the contract with the customer
2. Identify the performance obligations
3. Determine the transaction price
4. Allocate the transaction price
5. Recognise revenue when (or as) the performance obligations are satisfied

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

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

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

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

Notes to the financial statements (continued)

1. Significant accounting policies (continued)

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

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

Donations
Monetary donations are recognised as revenue when the Company gains control of the contribution or the right to receive the contribution. Non-monetary donations are not recognised as revenue where they cannot be reliably measured.

(b) Interest income

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

(c) 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 2023

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.

Notes to the financial statements (continued)

1. Significant accounting policies (continued)

(m) Critical accounting estimates and judgements

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

Key estimates – revenue recognition
There is significant judgement involved in determining whether a funding contract includes sufficiently specific performance obligations. 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.

Notes to the financial statements (continued)

	2023 $	2022 $
2. Revenue from operations		
Revenue from contracts with customers – AASB 15 (recognised over time)		
Government funding	6,328,583	1,767,060
Funding and grants from corporate and institutional funding bodies	6,961,594	2,240,287
	13,290,177	4,007,347
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	654,292	1,459,743
In-kind contribution	525,000	-
Donations	-	925,000
	11,179,292	12,384,743
Total revenue from operations	**24,469,469**	**16,392,090**

	2023 $	2022 $
3. Service provider and projects expenses		
Amounts paid or distributed to service providers for projects	14,710,879	12,584,110
	14,710,879	**12,584,110**
4. Consulting and support services expenses		
Consulting and administration	1,036,725	504,667
Legal costs	221,528	100,428
Other costs	86,085	49,647
	1,344,338	**654,742**
5. Cash and cash equivalents		
Cash at bank	61,600,309	20,349,099
	61,600,309	**20,349,099**
6. Receivables		
Trade receivables	1,108,132	265,811
ATO receivable	-	140,422
	1,108,132	**406,233**
7. Other assets		
Accrued revenue	1,511,856	35,315
	1,511,856	**35,315**
8. Plant & equipment		
Computer equipment	11,700	2,662
Accumulated depreciation	(2,662)	(1,775)
	9,038	**887**
9. Contract liability		
Income received in advance	35,809,568	3,435,507
	35,809,568	**3,435,507**

Notes to the financial statements (continued)

	2023	2022
	$	$

10. Trade payables and accruals

Trade and other payables	469,078	546,389
ATO payable	3,060,129	-
Accruals	2,488,415	1,230,928
	6,017,622	**1,777,317**

11. Provision

Provision for employee leave entitlements	69,631	57,691
	69,631	**57,691**

12. Accumulated funds

Accumulated funds at the beginning of the financial year	15,521,019	13,756,552
Surplus for the year	6,811,495	1,764,467
Accumulated funds at the end of the financial year	**22,332,514**	**15,521,019**

13. Reconciliation of cash flows from operating activities

Surplus for the year	6,811,495	1,764,467
Add: depreciation	887	887
Changes in assets and liabilities		
Change in receivables	(701,899)	(374,133)
Change in other assets	(1,476,541)	(9,732)
Change in contract liability	32,374,061	(1,162,893)
Change in trade and other payables	4,240,306	(330,934)
Change in provisions	11,940	25,874
Cash flows from operating activities	**41,260,249**	**(86,464)**

14. Auditor remuneration (Grant Thornton)

Audit services	33,000	21,000
Other services	24,000	2,000
	57,000	**23,000**

15. Contingencies

The Company had no contingent liabilities as at 30 June 2023 and 30 June 2022.

Australian Genomic Cancer Medicine Centre Limited
30 June 2023

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 $842,812 to key management personnel during the year (2022: $437,918). There were no other transactions with key management personnel during the year ended 30 June 2023. Key Management Personnel include Board members, the Chief Executive Officer (CEO), the Deputy Chief Executive Officer, the Chief Financial 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.

For a part of the year, while the CEO was on personal leave, former Board member, Bruce Goodwin executed the role of CEO and was remunerated for his services as the Acting CEO of the Company. This engagement was governed by an Agreement for Supply of Professional Services between the Company and Bruce Goodwin as a Director of Sundial Management Pty Limited. This remuneration is included in the above-noted amount paid to key management personnel.

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

During the year, the Company entered into an Agreement for Supply of Professional Services with the spouse of former Board member, Bruce Goodwin, as a Director of Sundial Management Pty Limited. As noted above, Bruce Goodwin is also a Director of Sundial Management Pty Limited. The Company paid $57,200 to this entity for project management services rendered.

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

Garvan Institute of Medical Research is a member of this entity and appoints a Director to the Board under this Company's constitution. Professor Benjamin Kile is the appointed Director of this Company, by the Garvan Institute of Medical Research. The previous appointed Director, Professor Nathan McGregor, resigned during the year. CEO and Board member, Professor David Thomas is a Faculty 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:

- From financial year 2020 to 2024 (inclusive), $4,740,798 is payable for IT infrastructure, Personnel and Director and Clinical Cohorts. During the year, $377,155 (2022: $848,323) was paid by this Company to Garvan Institute of Medical Research for these services. From 1 January 2023, the Company entered into a new agreement for the provision of IT Professional Services by Garvan Institute of Medical Research for $500,000 per annum.

Notes to the financial statements (continued)

17. Related party transactions (continued)

- From financial year 2020 to 2024 (inclusive), an estimated $10,688,500 is payable for screening and sequencing activities and a further $3,771,375 for activities at other sites. These payments are contingent on contractual milestones being met by the service provider. During the year, $2,758,375 (2022: $4,551,313) was paid by this Company to Garvan Institute of Medical Research for these activities.

- From financial year 2020 to 2024 (inclusive), $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, $202,592 (2022: $196,691) 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 provided this Company access to a licensed area on a pro-bono basis. This agreement ceased during the year.

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, $4,372,258 (2022: $4,451,940) was paid to that entity by this Company under this agreement. An additional $527,625 was paid to the University under a separate agreement for molecular screening and a further $270,704 (2022: $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). Bruce Goodwin is also a Board member of Rare Cancers Australia. 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 (2022: $500,000) was paid to that entity during the year.

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

Central Adelaide Local Authority Network provides general and quaternary hospital services. Professor Michael Brown has been appointed as a representative member on the Board. A payment of $20,000 was made in the year (2022: $22,000) 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 $780,100 has been made in the current year (2022: $789,650) towards research services provided by University of Melbourne.

Australian Genomic Cancer Medicine Centre Limited
30 June 2023

Notes to the financial statements (continued)

17. Related party transactions (continued)

During the year, CEO, Professor David Thomas was appointed the Director of the Centre for Molecular Oncology at the University of New South Wales (UNSW). The Company has the following agreements with UNSW:

- The Company has a Research Collaboration Agreement with UNSW and received $352,234 from the University during the year under this agreement.

- The Company has entered into a Master Research Services Agreement with UNSW commencing post year-end. Under this agreement, the Company will pay approximately $5,080,245 over two years to UNSW for research services delivered by the University.

- The Company has also entered into a Collaboration Space Agreement with the University for the usage of specified University's premises for the term of the agreement for approximately $150,000.

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 2023.

18. Events subsequent to balance date

Other than the above-noted Master Research Services Agreement with UNSW commencing post year-end, there are no material events subsequent to balance date.

19. Entity details

The registered office of the Entity is University of NSW, L6 Hilmer Building (E10), Union Road, Kensington NSW 2052. 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 2023

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

30 August 2023

Australian Genomic Cancer Medicine Centre Limited
30 June 2023

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 2023 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 2022; 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:

Paul Jeans
Chair of the Board of Directors

Tze Masters
Director

Sydney

30 August 2023

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Auditor's Independence Declaration

To the Responsible Entities of Australian Genomic Cancer Medicine Centre Limited

In accordance with the requirements of section 60-40 of the *Australian Charities and Not-for-profits Commission Act 2012*, as lead auditor for the audit of Australian Genomic Cancer Medicine Centre Limited for the year ended 30 June 2023, 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, 30 August 2023

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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 2023, and the statement of profit or loss and other comprehensive income, statement of changes in funds and statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies and the Responsible Entities' declaration.

In our opinion, the financial report of Australian Genomic Cancer Medicine Centre Limited has been prepared in accordance with the requirements of Division 60 of the *Australian Charities and Not-for-profits Commission Act 2012* ("ACNC Act"), including:

a) giving a true and fair view of the Registered Entity's financial position as at 30 June 2023 and of its financial performance for the year then ended; and

b) complying with Australian Accounting Standards *AASB 1060 General Purpose Financial Statements -Simplified Disclosures for For-Profit and Not-for-Profit Tier 2 Entities* and Division 60 of the *Australian Charities and Not-for-profits Commission Regulation 2022.*

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 (including Independence Standards)* (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, 30 August 2023

Omico.

Australian Genomic Cancer Medicine

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