OUTSMARTING CANCER TOGETHER

ANNUAL REPORT

AUSTRALIAN GENOMIC CANCER MEDICINE CENTRE

2019

at a glance

Not-for-profit

company limited by guarantee

GOVERNED BY A BOARD

10 Directors plus the CEO

9 CORPORATE MEMBERS

MANY COLLABORATORS AND PARTNERS MAKING OUR PROGRAMS A SUCCESS

MANY SUPPORTERS WORKING WITH US TO MAKE A DIFFERENCE

Finance & Risk

AS AT 30 JUNE 2019

$8.9M in the bank

$10M + $67k interest income

$1.15M expenses

NEXT 2 QUARTERS

$10.2M income

$6.64M expenses

POTENTIAL HIGH IMPACT RISKS

- STRATEGY FOR GROWTH NOT WELL DEFINED
- INSUFFICIENT FUNDS TO MEET DEMAND
- QUALITY CONTROL AND OPERATIONAL FAILURE
- LEGAL & REGULATORY COMPIANCE FAILURE
- HEALTH & SAFETY OF PATIENTS
- LOSS OF KEY PERSONNEL
- FAILURE TO MEET CONTRACTUAL OBLIGATIONS

MoST

molecular screening and therapeutics study

2016 - 2019

1673 PATIENTS SCREENED

64% with treatment recommendations

number of patients enrolled in novel therapy studies **185**

1 substudy is closed and in analysis phase
2 substudies are in follow-up phase
2 substudies are recruiting
2 substudies are in start-up

3 new substudies opening in Q4 2019

7 new concepts and proposals in development

RisC

genetic cancer risk in the young

2016 - 2019

1092 PATIENTS ENROLLED

55% female

participants that have had multiple primary cancers **20%**

61 participants enrolled in an annual surveillance program

11 participants have had 14 asymptomatic cancers identified and treated

about us

Who we are:

Australian Genomic Cancer Medicine Centre is a national not for profit organisation bringing together major cancer treatment centres, leading research institutions and industry to deliver the next generation of treatment options and better outcomes to Australian cancer patients.

We are a:

- national vehicle for unifying Australia's leading cancer and research centres
- fit-for-purpose and commercially nimble mechanism for engagement with the pharmaceutical and business sectors
- sustainable business model for genomic medicine in the mid- to longer term
- partnership that delivers research outcomes

What we do:

We put patients first

Our vision:

Australian Genomic Cancer Medicine Centre envisions an Australia where every cancer patient has access to the innovative therapies and is a partner in a clinical research program that will continue to deliver the next generation of treatment options.

Our work:

We are a national genomics-based precision medicine alliance bringing together like-minded organisations to apply the principles of precision medicine to:

- bridge the gap – to bring the next generation of healthcare to cancer patients
- use innovation to inform the new "standard of care" for cancer patients
- stimulate innovative research into the prevention, earlier diagnosis and better treatment of cancers with unmet need
- increase access of Australian patients with cancer to innovative therapy

We build partnerships between governments, community, academic institutions and industry.

Our values:

We actively encourage and engage in **innovation**.

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

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

We act with **integrity** and **compassion** to fight for **equity of access.**

strategic goals

Our goal is to be the organisation of choice for industry, government and community to partner with, for the purposes of providing access, data, innovation and expertise, through its national member network, to deliver clinical innovation, implement policy change and bring benefit to Australian cancer patients.

Innovation

Our goal is to leverage the expertise of our members, collaborators and partners to support patient access to advanced technologies, infrastructure and novel methodologies; creating a dynamic environment for innovation.

Translation and Engagement

We are a new ecosystem that brings together clinicians and researchers around Australia with industry and governments to accelerate the integration of genomic and translational research and access to novel therapies into clinical practice.

Through ongoing enagement, we will become a trusted voice and advisor to shape the future of Australian precision oncology policy and practice.

Connection and Empowerment

We are developing an internationally unique set of data, linking the biological, genetic and clinical characteristics of thousands of individuals with cancers with high unmet need or early onset to guide clinical decisions and inform discovery research.

By building and consolidating our national network we will drive the development of cancer therapies, understand and exploit genetic predisposition, integrate health economics and therapeutic implementation, and train the next generation of clinicians/scientists.

Sustainability

We are developing programmatic relationships with pharmaceutical companies, financial insitutions and philanthropic agencies to secure funding for trials, research collaborations, and correlative science. The long-term plan is to expand and grow the AGCMC platform.

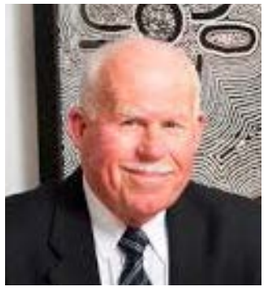
people
are our success

our board

Emeritus Professor Mark Wainwright AM (Chair)

Mr Richard Vines (Deputy Chair)

Professor David Thomas (CEO)



Mr Paul Jeans Chancellor, University of Newcastle (NSW)

Professor Chris Goodnow (Garvan Institute of Medical Research)

Mr Bruce Goodwin (for Medicines Australia)

Professor John Simes (for University of Sydney)

Professor Kathryn North AO (for Australian Genomic Health Alliance)

Professor Michael Brown (Member representative)

Professor Ricky Johnstone (Member representative)

Ms Tze Masters

A/Professor Paul Martin (Company Secretary)

our leadership team

Professor David Thomas
CEO

Dr Vera Terry
Deputy CEO

Dr Mandy Ballinger
Head, Clinical Cohorts

Dr Lucille Sebastian
Program Manager

our members

- Peter MacCallum Cancer Centre (VIC)
- The Australian Capital Territory (ACT), represented by ACT Health (Canberra Hospital)
- Metro South Hospital and Health Service (QLD) (Princess Alexandra Hospital)
- Central Adelaide Local Health Network Incorporated, represented by Royal Adelaide Hospital (SA)
- The State of Tasmania (represented by its Department of Health) (Tas) (Royal Hobart Hospital)
- Garvan Institute of Medical Research (NSW)
- University of Sydney (NSW), represented by the NHMRC Clinical Trials Centre
- Linear Clinical Research Limited (WA) (Sir Charles Gairdner Hospital)
- Northern Territory of Australia, represented by Top End Health Service (NT) (Royal Darwin Hospital)

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

some of our collaborators

Department of Health
GOVERNMENT OF WESTERN AUSTRALIA
PathWest LABORATORY MEDICINE WA
rare cancers AUSTRALIA
Centre for Cancer Biology
MACQUARIE University
Walter+Eliza Hall Institute of Medical Research
DISCOVERIES FOR HUMANITY
ST VINCENT'S HOSPITAL SYDNEY
BioGrid Connecting health information
QIMR Berghofer Medical Research Institute

some of our supporters

NSW GOVERNMENT Health
Medicines Australia
CRBF Cooper Rice-Brading Foundation
AstraZeneca
Roche
Australian Genomics Health Alliance
illumina
BAYER
Leukaemia Foundation
VISION TO CURE
MISSION TO CARE

program governance

Program Steering Committee (PSC)

Role: To define the strategic direction of the Program

Chaired by David Thomas (CEO)

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

PSC Executive Group (PSCEG)

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

Chaired by David Thomas (CEO)

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

Working groups:

Clinical trials (CTWG)

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

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

Early Detection and Risk (EDRWG)

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

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

Molecular Pathology (MPWG)

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

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

Patient Support and Advocacy (PSAWG)

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

Chaired by Richard Vines (RCA)

Data Curation and Integration (DCIWG) & International Program Linkage (IPLWG)

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

Chaired by Clare Scott (WEHI)

advantages

that only we can provide

Report from the Chair of the Board

I am most honoured to have been appointed the inaugural Chair of the Board of the Australian Genomic Cancer Medical Centre. 2019 has been a busy year for the Board and its sub-committees. The AGCMC is a not-for-profit company and its Board comprises member directors and independent directors with a broad range of business, pharmaceutical industry, research and clinical medicine experience.

The Board has made the appointments of Professor David Thomas as CEO, Dr Vera Terry as Deputy CEO and Mr Paul Martin as Company Secretary. David's outstanding leadership and record of achievement as an oncology clinician/researcher, along with the great support of Richard Vines, Deputy Chair of the AGCMC and co-chair of Rare Cancers Australia, were responsible for the award of the $50 Million Federal Government's grant. Vera's experience at the National Health & Medical Research Council Clinical Trials Centre at Sydney University and her qualifications in medical science and law have been invaluable in getting the contractual arrangements with the member organisations in place. I have worked with Paul Martin for the past 11 years in his role as Company Secretary of two other not-for-profit companies in the areas of research and education. He is an extremely well qualified and experience company secretary who plays an invaluable role at the AGCMC in ensuring good governance.

The AGCMC is a truly national organisation with research/clinical institutions in all states and territories. The molecular screening is being driven by NSW, South Australia, Victoria, Western Australia and Queensland, and the expansion into the haematological cancer space is being led out of Queensland and South Australia.

The active participation of the pharmaceutical companies is critical to the program. Bruce Goodwin, Managing Director, Janssen-Cilag Pty Ltd, represents Medicines Australia on the Board and plays a major role as Chair of the Finance, Risk & Audit Committee (FRAC). The FRAC has worked very actively with the CEO, Deputy CEO and Company Secretary, in establishing the audit, finance & risk management arrangements for the company.

The active participation of all member organisations, the community, along with pharmaceutical and financial companies, will ensure that the AGCMC has a sustainable future beyond the five year grand provided the Commonwealth Government.

Emeritus Professor Mark Wainwright AM

Report from the Chief Executive Officer

Dear colleagues

This is our first annual report for the AGCMC. We are now 9 months old, but growing fast. There have been several key highlights of the first year of our existence. First, the creation of a no-for-profit company whose members comprise the leading cancer centres in every Australian state and territory must surely rank as one of the most remarkable steps forward in enabling precision oncology nationally. It is an under-appreciated fact that the enduring nature of incorporated entities makes possible permanent changes to the clinical trials landscape. The truth of this will emerge over the next few years. Second, the establishment of the AGCMC office at Garvan Insitute of Medical Research, together with the recruitment of an excellent deputy CEO in Dr Vera Terry, has made the AGCMC real. Vera has been working on building the structural components - such as the clinical trials and molecular pathology working groups, the cancer risk committee, and data and international partnerships committees - of the AGCMC through which its members will work to achieve our ambitious goals, about which more below. Vera is also working hard on a communications strategy for the AGCMC, an increasingly important matter as we reach into the community for partnerhsips. Operationally, we have a solid foundation for our finances, including engaging Mr Satish Nair as our accountant and finance officer, as well as putting the appropriate insurances in place. The Board has appointed a company secretary, Mr Paul Martin, who has created the formal processes that enable the Board to function in directing the AGCMC. Finally, we have completed the major four contracts with our key partners, the Garvan, NHMRC Clinical Trials Centre (University of Sydney), Rare Cancers Australia, and Biogrid.

While all of that has been going on, and building on the previous program funded within NSW, the program has reached more than 1,500 subjects enrolled onto MoST, and over 1,000 onto RisC. We are now open in 3 states and territories, and will have completed the national roll-out by the end of 2019. Our clinical trials portfolio is growing, with 3 trials completed, 2 under way, and four in late development. There have been more than 30 publications to date, and more underway in 2019/20, to share with the clinical and research community what we have learnt to date.

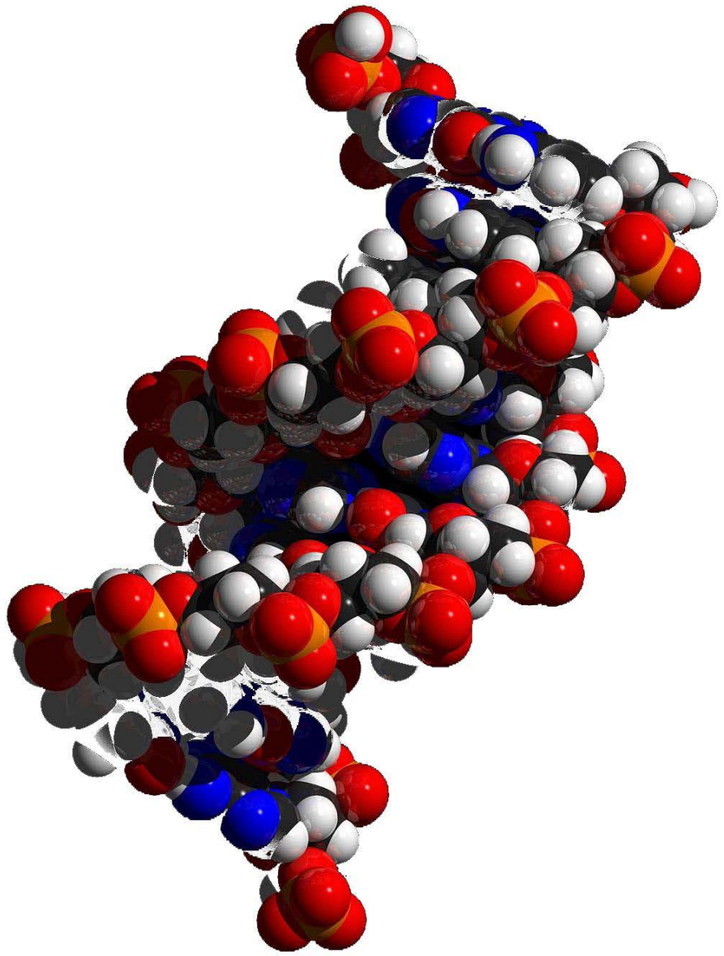
The program has solicited interest and investment from a diverse group of stakeholders, including the pharmaceutical and biotechnology sector, community organisations and philanthropy. All of these activities not only ensure that we remain in the black, but allow us to expand the number of Australians that we can reach with the promise of precision oncology.

Looking to the future, we are working hard to maximise the leverage of co-investment in the AGCMC. In addition to those outlined above, potential stakeholders include other health and community organisations with which we interact operationally or strategically. We are aiming to build a network of strong collaborative supporters, who share our vision to create a sustainable future for precision oncology research and care, and one that reaches as many Australians as possible. Our goal is to become an essential part of the Australian clinical cancer research landscape, by integrating research into a standard of care.

Professor David Thomas FRACP, PhD

solutions

that will change the world



Comprehensive molecular profiling of patient tumours over the past few years has led to the development of a new discipline termed "precision medicine".

In oncology, precision medicine is used to precisely characterise the molecular and cellular features of a tumour, as well as those of its microenvironment, and explore treatment approaches that are expected to confer benefit to an individual or population. Molecular profiling helps identify changes that can serve as biomarkers of cancer growth, resistance to conventional cancer treatment and patient outcome. Many molecular changes exist in multiple tumour types.

Molecular profiling is becoming standard practice for many patients with advanced disease, replacing the traditional treatment paradigm of prescribing standard chemotherapy/ radiotherapy based upon the tumour's organ of origin, histology, and stage, regardless of their biological makeup.

By understanding the molecular profile of a cancer, clinicians can better select a treatment that will most effectively benefit the patient, significantly improve patient outcomes, and at the same time, reduce the unnecessary time, cost, and physical and emotional stress incurred through the traditional, iterative clinical approach.

Recent clinical trials for some anticancer drugs (pembrolizumab – PD-1 inhibitor; larotrectinib – TRK inhibitor) have shown unprecedented, extended survival in patient populations that are enriched with individuals bearing tumours with specific molecular alterations, such as gene mutations, amplifications and translocations, and microsatellite instability.

Scientific and technological advances go hand in hand, leading to improved therapeutic choices. There is growing acceptance of biomarker testing for the purpose of targeting treatment of advanced cancer. Centres for Medicare & Medicaid Services (CMS, USA) recently approved companion diagnostics (March 2018) for patients with advanced cancer to identify certain genetic mutations that may benefit from U.S. Food and Drug Administration (FDA)-approved treatments. Additionally, when a known cancer mutation cannot be matched to a treatment then the results can help determine a patient's candidacy for cancer clinical trials.

Precision medicine treatments can come with a higher price tag than traditional therapies as the cost of an individual test to match a patient with a precision therapy is often more expensive than standard screening. However, from a value-based perspective, precision medicine has the potential to lower costs overall by reducing the need for additional testing and enabling clinicians to prescribe effective therapies earlier.

By replacing a trial-and-error based approach with a targeted approach that improves patient outcomes, we are helping to make the economic case for precision medicine.

projects

that drive our research

Cancer Molecular Screening and Therapeutics (MoST): a framework for multiple, parallel signal-seeking studies of targeted therapies for all cancers.

Molecular tumour profiling has now entered clinical practice, driven by capacity, reduced costs, and the enormous unmet need for effective treatments for advanced cancers. MoST tests a novel paradigm for evaluating biomarker-driven treatments for patients with advanced cancer, with a particular focus on rare and neglected cancers.

A master protocol provides a framework for profiling tumours for actionable molecular targets and for recommending treatments based on the molecular signatures of tumours. This in turn allows for the development and conduct of multiple, parallel, phase 1b/2a clinical sub-studies of novel treatments or indications for eligible patients based on a common structure.

This ground-breaking program has already enrolled more than 1,000 Australians with advanced cancers, more than 80% of which are rare and less common. Patients with no other effective therapeutic options have travelled from every state and territory to NSW to take part in the program. More than 180 people have gone on to receive novel therapies over the past two years.

The target population comprises patients with pathologically confirmed advanced or metastatic solid cancers of any histological type, either during or after their last line of effective therapy, with a particular focus on rare or less common cancers.

Based on tumour profiling data, patients may be deemed potentially eligible for treatment in a MoST substudy or may be recommended to a suitable clinical trial, or an off-label therapy if available and appropriate.

There are three categories of actionable variants:

- mutations that mean the patient is suitable for a MoST substudy;
- mutations for which an existing funded or unfunded drug is available; and
- mutations that mean the patient is suitable for an existing clinical trial.

Two general classes of drugs are used in MoST substudies:

- drugs approved for clinical use in Australia by the Therapeutic Goods Administration (TGA), but not for the indication being treated;
- drugs not approved for clinical use in Australia by the TGA, but which are being tested in phase 1b/2a or 3 clinical trials for other indications, or are registered outside Australia.

The drugs employed will have well characterised toxicity profiles and established dose and administration schedules.

MoST Screening exceeding recruitment targets:

635 patients have been screened since January 2019, bringing the total number of patients screened since September 2016 to 1673. This total number is currently more than 52% above our expected screening target for September 2019.

With 1673 patients enrolled in the MoST Program since September 2016 our recruitment is 572 above the number of patients anticipated.

Figure 1 shows the current distribution of recruitment across the country.

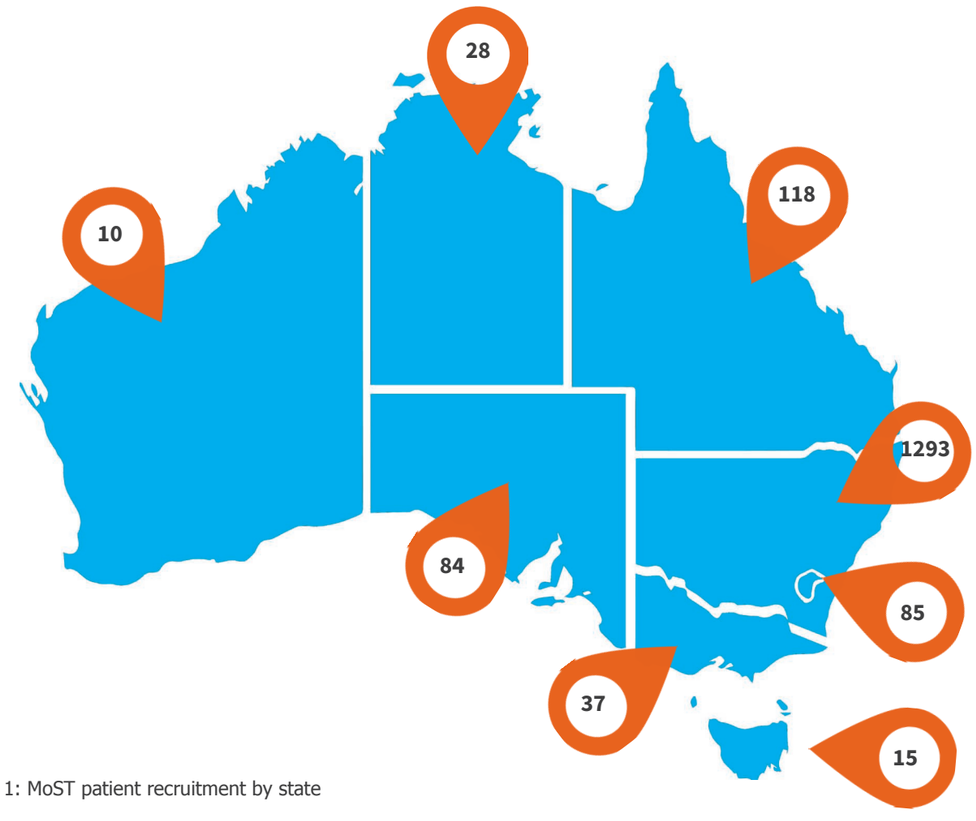
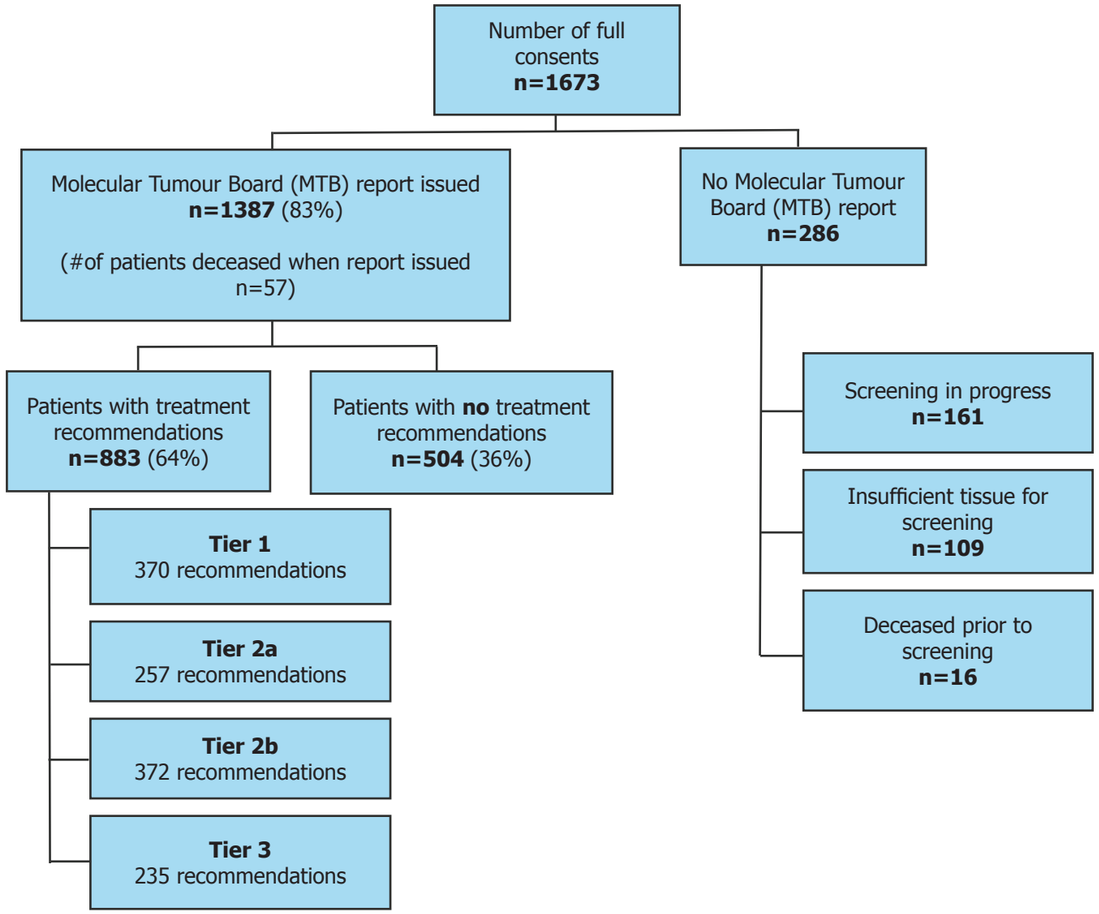


Figure 1: MoST patient recruitment by state

Of the 1637 patients enrolled, 1387 (83%) have had an Molecular Tumour Board (MTB) report issued. 535/1673 (32%) of patients are deceased, with 73/535 (14%) deceased prior to the completion of molecular screening. Treatment recommendations have been made to 883 patients.



Notes:

Patients can have more than one recommendation and can be counted in more than one Tier category.

Treatment recommendations fall into 3 categories:

- Tier 1 - evidence of tumour mutations that render the patient suitable for treatment in a MoST sub-study,
- Tiers 2a and 2b- evidence of tumour mutations for which an existing funded or unfunded drug is available
- Tier 3 - evidence of tumour mutations that render the patient suitable for an existing clinical trial outside of MoST sub-studies

MoST Therapeutics

The novel basket trial design, the potential for efficient addition of sub-studies under the unique MoST framework protocol, extreme patient demand, engagement with the pharmaceutical industry and national expansion of the program has resulted in increased clinical trials capacity.

Recruitment Sites:

Recruiting centres in NSW include St Vincent's Hospital, St George Hospital and the Chris O'Brien Lifehouse.

Nationally, the Canberra Hospital (ACT) and Linear Clinical (Western Australia) are open to the program.

Site start-up and governance review is underway with the Peter MacCallum Cancer Centre (Victoria), the Princess Alexandra Hospital (Queensland), The Royal Darwin Hospital (Northern Territory), The Royal Adelaide Hospital (South Australia) and the Royal Hobart Hospital (Tasmania).

Current status of MoST Sub-studies

Study	Status	Description
Palbociclib	In close-out	Single arm, open label, signal seeking, phase Ib/IIa trial of the DK4/6 inhibitor palbociclib in patients with tumours with amplified Dtype cyclins or CDK4 or inactivation of CDKN2A
Durvalumab and tremelimumab	Patients on treatment and in follow-up	Study to assess the clinical activity of durvalumab and tremelimumab in patients grouped post-hoc on the basis of tumour expression of PDL-1, TIL and MTB. Durvalumab and Tremelimumab are mAB blocking immune checkpoint inhibitors PD-1 and CTLA-4 respectively to control/eliminate tumours
Olaparib and durvalumab	Patients on treatment and in follow-up	Olparib is a PARP inhibitor, which targets cancers with defects in HR DNA repair (BRCA1/2 mutations). Durvalumab blocks the PD-1/PDL-1 pathway relieving PDL-1 mediated suppression of T-cells activation
Vismodegib	Now recruiting	Vismodegib in patients with tumours harbouring PTCH1 or SMO mutations
Eribulin	Now recruiting	Sacroma or EHE patients harbouring CD31+ expressions
Larotrectinib	In start-up	CNS or non-CNS patients harbouring NTRK1-3+ expressions
TDM1 (Kadcyla)	In start-up	
Tremelimumab	In development	

There are an additional 3 concepts in the clinical Sub-study protocol development phase and another 4 proposals for concepts are in the pipeline.

Genetic Cancer Risk in the Young (RisC)

Gene mutations can be somatic or germline. Somatic mutations happen spontaneously and occur after birth. Germline mutations are inherited, that is, they are present at birth.

Tumour genetic (somatic) testing detects mutations that may actually be germline alterations, but germline alterations require confirmation in matched normal samples (eg, DNA extracted from white blood cells, buccal swabs, or cultured skin fibroblasts).

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

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

We believe that mapping cancer risk in early-onset cancer populations will lead to a better understanding of the heritable drivers of disease and enable better monitoring and prevention measures, treatment options and lifestyle and reproductive choices. The RisC study uses genomics as the basis for a series of innovative and practice-changing clinical programs.

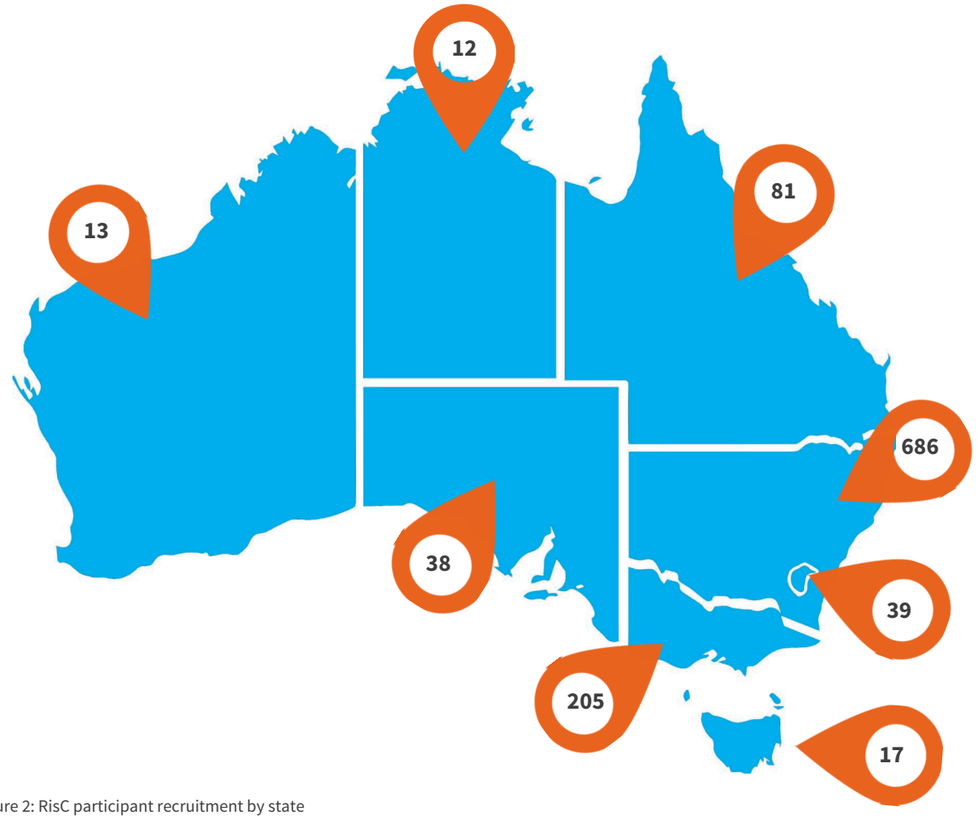


Figure 2: RisC participant recruitment by state

A whole-genome sequencing program is used to map genetic cancer risk and identify individuals at increased heritable risk of developing cancer.

Individuals at increased cancer risk are then invited to participate in a surveillance program aimed at early cancer detection.

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

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

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

At the time of this report, 1120 cancer probands* across Australia (Figure 2) (55% female) have been enrolled onto the RisC study. More than 20% of probands have had multiple primary cancers, and diverse cancer types have been observed (Figure 3).

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

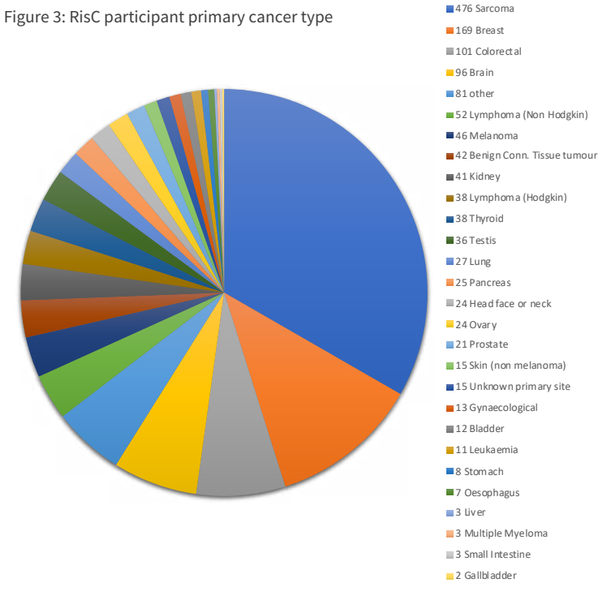
There are no surveillance recommendations for many hereditary cancer syndromes that predispose individuals to cancers that may arise anywhere in the body (multi-organ).

The surveillance in multi-organ cancers (SMOC+) study aims to estimate the prevalence and incidence of investigable lesions using protocols (including whole-body Magnetic Resonance Imaging (MRI)) customised by genotype for individuals at increased risk of cancer. Participation in the surveillance pahse of the RisC study involves annual whole-body MRI, physical examination and clinical review, blood test and completion of questionnaires.

To date fourteen new asymptomatic cancers have been identified in eleven individuals that have subsequently been treated with curative intent. We currently have 61 people under annual surveillance.

Mapping genetic cancer risk at the population level and identifying those at risk will lead to better monitoring and prevention strategies, treatment options and more informed lifestyle and reproductive choices.

Figure 3: RisC participant primary cancer type



support

for patients and clinicians

Rare Cancers Australia (RCA).

Rare Cancers Australia has initiated activitites in keys service areas as follows:

Patient Support Program – The RCA Patient Care Team is currently providing support via direct contact (verbal or written) to 311 patients with either rare or less common cancer. In the period 1 January to 30 June RCA has provided verbal or written support to 11 new patients. Of these 64 patients have been provided information about and referred to the AGCMC Program (MoST)

Centre Visits – RCA staff have visited 2 sites (Sydney and Melbourne) and are scheduling visits to the remaining sites over the coming months.

Web presence – RCA has commissioned the design of a new patient centric website with work expected to be completed by 31 December 2019. To further enhance the site RCA has also commissioned production of a series of easily understood videos that will explain complex subjects such as clinical trials, genomic medicine and patient rights.

Data collection within the RCA program – RCA has installed a tracking system that will enable RCA to provide accurate metrics over the course of the AGCMC program and beyond.

Patient Advisory Board – RCA has established a 12 person Patient Advisory Board to provide constant input on initiatives including patient care design,videos, website, social media and patient friendly events.

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

Advocacy & awareness – RCA staff have manned information booths at both the Cancer Nurses Conference and the Medical Oncology Group of Australia ASM in Canberra. Both events have provided excellent opportunities to raise awareness of the AGCMC within the HCP Communities.

Additionally RCA is conducting an ongoing media campaign on the subject of genomic science and is planning a major event on November 28 2019 in Parliament House, Canberra. This event will be supported by a major report detailing the opportunities presented by genomic medicine.

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

- Resolution of the issue of ownership and costs relating to access to tumour blocks stored with pathology laboratories.
- Campaigning for the reform of MSAC processes as they apply to various genetic testing.
- Advocating for more widespread availability of pre-emptive screening based on genetic profile of patients

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

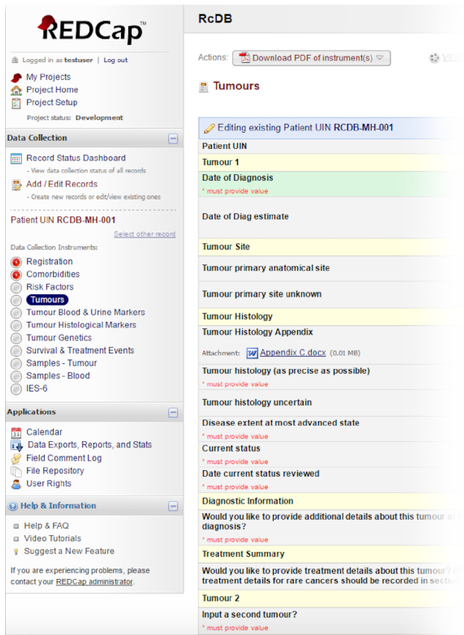
Communications - RCA has retained communications consultants to develop a three phase strategy to engage media in each of the clinical sites as opportunities arise. This campaign is expected to roll out progressively throughout 2020.

Rare Cancer Portal

The collection, aggregation, analysis and transferability of data from patients and clinical trials is key to streamlining care and research for rare cancer patients.

A decision was made to embed the Rare Cancer Portal within BioGrid Australia. Biogrid Australia is a Melbourne based, not for profit company owned by the research sector. In 2009, BioGrid was licensed by its members to operate the existing BioGrid Australia data connectivity platform. Data governance and patient privacy are at the core of BioGrid's federated data sharing platform that securely links patient level clinical, bio-specimen, genetic variance, imaging and administrative datasets from multiple sources for the purpose of ethically approved medical research.

Portal planning, both project and financial, has commenced and is being led by the Portal lead, Professor Clare Scott and BioGrid Australia CEO, Maureen Turner. Key performance indicators (KPIs) for the project have been defined and detailed planning commenced for the recruitment of the project and clinical staff. Database development, ethics considerations and design. Modeling of the WEHI Stafford Fox Rare Cancer Program, which underpins the research aspects of the rare cancer Portal is underway with four staff members who will be an integral part of the Portal: the medical oncologist, the genetic counsellor, the project coordinator and the software designer.



outputs

from our research

Publications

1. Ballinger ML, Pinese M and Thomas DM (2019). Translating genomic risk into an early detection strategy for sarcoma. Genes Chromosomes Cancer 58: 130-136.
2. Best M, Bartley N, Jacobs C, Juraskova I, Goldstein D, Newson A, Savard J, Meiser B, Ballinger M, Napier C, Thomas D, Biesecker B, Butow P. (2019) Patient perspectives on molecular tumour profiling: 'Why wouldn't you?'. BMC Cancer; 19:753
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Presentations

International

1. March 2019, D Thomas Invited speaker - e-ASIA "Rare Cancer" workshop, Singapore: Precision oncology
2. March 2019 D Thomas Invited speaker - International Medical Education Leaders Forum (IMELF) Australasia, March, Auckland, New Zealand): The Australian Genomic Cancer Medicine Program
3. April 2019 D Thomas Invited speaker - Maine Cancer Genome Initiative Annual Meeting, Maine, USA : The Molecular Screening and Therapy Study
4. May 2019 M Ballinger Invited speaker - Scandinavian Sarcoma Group 39th Plenary Meeting, Li Fraumeni Workshop, Bergen, Norway, Surveillance in Li Fraumeni syndrome
5. May 2019 M Ballinger Invited speaker - Scandinavian Sarcoma Group 39th Plenary Meeting, Li Fraumeni Workshop, Bergen, Norway, Psychosocial impact of surveillance in Li Fraumeni syndrome
6. May 2019 D Thomas Invited plenary speaker - Scandinavian Sarcoma Group 40-year Jubilee meeting, Bergen, Norway : Genetics and Oncologic Therapy
7. June 2019 M Best - 17th International Conference on Communication, Medicine and Ethics, Adelaide, Australia
8. June 2019 M Best - European Human Genetics Conference, Gothenberg, Sweden, Advanced cancer patient perspectives on consenting to molecular tumour profiling
9. June 2019 S Thavaneswaran - ASCO Annual Meeting, Chicago, USA, Medical Oncologists' experiences with returning molecular tumour profiling to patients.
10. June 2018 M Best - European Meeting on Psychosocial Aspects of Genetics, Milan, Italy, Young cancer patient perspectives on undertaking whole genome sequencing: A qualitative study
11. September 2018 M Best - International Conference on Communication in Healthcare, Porto, Portugal, Returning Genetic Results and Communication about Genetic Risk in Cancer

Presentations

National

1. March 2019 D Thomas Invited speaker - International Academy of Pathology (IAP) meeting, Sydney : Biomarker-driven trials
2. March 2019 D Thomas Invited speaker - Drug Development Conference 2019, March, Sydney : Precision oncology trials
3. April 2019 M Ballinger Invited speaker - Sydney Children's Hospital Paediatric Oncology Journal Club, Sydney : Surveillance in Li Fraumeni Syndrome
4. June 2019 N Bartley - Sydney Catalyst Postgraduate and Early Career Researcher Symposium, Sydney : Uncertainty experienced by adults undertaking cancer genome sequencing: Systematic review
5. May 2018 M Best - Sydney Catalyst Postgraduate and Early Career Researcher Symposium, Sydney : Young cancer patient perspectives on undertaking whole genome sequencing: A qualitative study (Oral)
6. May 2018 C Napier - Sydney Catalyst Postgraduate and Early Career Researcher Symposium, Sydney : Young cancer patient perspectives on undertaking whole genome sequencing: A qualiative study (Poster)
7. May 2018 N Bartley - Sydney Catalyst Postgraduate and Early Career Researcher Symposium, Sydney : Advanced cancer patient perspectives on undertaking molecular tumour profiling: A qualitative study (Poster)
8. June 2018 C Napier - Australian Society for Medical Research ASM, Sydney : Young cancer patient perspectives on undertaking whole genome sequencing: A qualitative study (Oral)
9. June 2018 N Bartley - Australian Society for Medical Research ASM, Sydney : Why do advanced cancer patients undertake tumour molecular profiling? (Oral and Poster)
10. September 2018 M Ballinger - Familial aspects of Cancer: Research and Practice (KConFab), Kingscliff QLD, Young cancer patient perspectives on undertaking whole genome sequencing: A qualitative study (Poster)
11. October 2018 N Bartley - Sydney Cancer Conference, Sydney : Advanced cancer patient perspectives on undertaking molecular tumour profiling: A qualitative study (Oral and Poster)
12. October 2018 C Napier - Sydney Cancer Conference, Sydney : Young cancer patient perspectives on undertaking whole genome sequencing: A qualitative study (Poster)
13. November 2018 N Bartley - COSA ASM, Perth: Young cancer patient perspectives on undertaking whole genome sequencing: A qualitative study (Poster)
14. November 2018 N Bartley - COSA ASM, Perth: Advanced cancer patient perspectives on undertaking molecular tumour profiling: A qualitative study (Oral)
15. November 2018 N Bartley - Sydney Cancer Research Network Postgraduate and ECR Symposium, Sydney : Young cancer patient perspectives on undertaking whole genome sequencing: A qualitative study (Oral)
16. November 2018 N Bartley - Sydney Cancer Research Network Postgraduate and ECR Symposium, Sydney : Advanced cancer patient perspectives on undertaking molecular tumour profiling: A qualitative study (Oral)

financials

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Australian Genomic Cancer Medicine Centre Limited

ABN 67 627 640 733

Financial Report

For the Period ended 30 June 2019

Contents

Corporate Information Statement

Australian Genomic Cancer Medicine Centre Limited

A company limited by guarantee and registered with the Australian Charities and Not-for-profit Commission.

ABN 67 627 640 733

Responsible Entities

The Directors of Australian Genomic Cancer Medicine Centre Limited (AGCMC):

Emeritus Professor Mark Wainwright AM (Chair)
Mr Richard Vines (Deputy Chair)
Professor Michael Brown
Mr Bruce Goodwin
Professor Christopher Goodnow
Mr Paul Jeans
Professor Ricky Johnstone
Professor Kathryn North
Professor John Simes
Professor David Thomas
Ms Tze Masters (appointed on 10th September 2019)

Company Secretary
Associate Professor Paul Martin

Chief Executive Officer
Professor David Thomas

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

Auditor
Grant Thornton

Statement of profit or loss and other comprehensive income

For the period ended 30 June 2019

	Note	2019 $
Revenue	2	10,000,000
Interest income		67,301
Total revenue and other income		**10,067,301**
Service provider costs	3	(750,000)
Professional services costs	4	(289,967)
Employee costs		(49,275)
Other administrative costs		(59,600)
Total costs		**(1,148,842)**
Surplus for the period		**8,918,459**
Other comprehensive income		
Total comprehensive income for the period		**8,918,459**

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

Statement of financial position

As at 30 June 2019

	Note	2019 $
Assets		
Current assets		
Cash and cash equivalents	5	8,910,102
Prepayments	6	577
Other assets	7	69,582
Total current assets		**8,980,261**
Total assets		**8,980,261**
Liabilities		
Current Liabilities		
Trade and other payables	8	61,802
Total current liabilities		**61,802**
Total liabilities		**61,802**
Net assets		**8,918,459**
Funds		
Accumulated surplus	9	8,918,459
Total funds		**8,918,459**

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

Statement of changes in funds

For the period ended 30 June 2019

	Accumulated funds $	Total Funds $
Balance at 20 July 2018 (date of incorporation)	**-**	**-**
Comprehensive income for the period		
Surplus for the period	8,918,459	8,918,459
Other comprehensive income for the period	-	-
Total comprehensive income for the period	8,918,459	8,918,459
Balance at 30 June 2019	**8,918,459**	**8,918,459**

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

Statement of cash flows

For the period ended 30 June 2019

	Note	2019 $
Cash flows from operating activities		
Receipts from grants		11,000,000
Payments to suppliers and employees		(2,157,199)
Interest received		67,301
Net cash flows from operating activities	10	**8,910,102**
Net change in cash and cash equivalents		8,910,102
Cash and cash equivalents at beginning of period		-
Cash and cash equivalents at end of period	5	**8,910,102**

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") was incorporated on 20 July 2018. This financial report is from the date of incorporation to 30 June 2019 (period). The report does not have prior year comparatives as it is AGCMC's first year of operation. AGCMC is domiciled in Australia. The principal registered address is L7 The Kinghorn Cancer Centre, 370 Victoria Street, Darlinghurst NSW, 2010.

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

The financial report was authorised for issue in accordance with a resolution of the Board on 4 October 2019.

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

Grant Funding
Government funding which is contingent upon certain outcomes, including the expenditure of certain amounts, is recognised as revenue only when those outcomes are achieved and only to the extent of the expenditure incurred. Funding received that has not achieved such outcomes is recognised as other payables. Funding which is not contingent upon certain outcomes is recognised as revenue when the entity obtains control of the funds, economic benefits are probable and the amount can be measured reliably.

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

(c) Expenditure
All expenditure is accounted for on an accruals basis.

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

Notes to the financial statements (continued)

1. Significant accounting policies (continued)

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

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

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

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

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

(h) Financial instruments
The Entity adopted AASB 9 Financial Instruments for the period ending 30 June 2019. 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.

Notes to the financial statements (continued)

1. Significant accounting policies (continued)

Financial liabilities

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

(i) Trade and other receivables

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

(j) Trade and other payables

Trade and other payables are stated at amortised cost.

(k) Critical accounting estimates and judgements

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

(l) New and revised accounting standards

During the current period, the Entity adopted all of the new and revised Australian Accounting Standards and Interpretations applicable to its operations which became mandatory. The adoption of these Standards has not impacted the recognition, measurement and disclosure of transactions. As noted above, the Entity has adopted AASB 9 *Financial Instruments* for the period-ended 30 June 2019.

(m) New accounting standards and interpretations

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

Notes to the financial statements (continued)

		2019 $
2.	**Revenue**	
	Government funding	10,000,000
	Total revenue	**10,000,000**
3.	**Service provider costs**	
	Service provider costs	750,000
	Total service provider costs	**750,000**
4.	**Professional services costs**	
	Consulting and accounting	215,817
	Legal costs	69,146
	Other costs	5,004
	Total professional services costs	**289,967**
5.	**Cash and cash equivalents**	
	Bank balance	8,910,102
6.	**Prepayments**	
	Prepayments	577
7.	**Other assets**	
	ATO receivable	69,582

There was no impairment loss recognised in the current period. The receivables are due between 30 and 60 days.

8.	**Trade and other payables**	
	Trade and other payables	58,667
	Credit card payable	3,135
		61,802

Notes to the financial statements (continued)

		2019 $
9.	**Accumulated funds**	
	Accumulated funds at the beginning of the financial period	-
	Surplus for the period	8,918,459
	Accumulated funds at the end of the financial period	**8,918,459**
10.	**Reconciliation of cash flows from operating activities**	
	Surplus for the period	8,918,459
	Changes in assets and liabilities	
	Change in prepayments	(577)
	Change in other assets	(69,582)
	Change in trade and other payables	61,802
	Cash flows from operating activities	8,910,102

11. Related party transactions

Key Management Personnel include board members, the chief executive officer and the Deputy Chief Executive Officer. 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.

Key management personnel compensation

The company paid $99,275 to key management personnel during the period.

Transactions with other related parties

There were no other related party transactions during the period ended 30 June 2019.

Notes to the financial statements (continued)

12. Contingencies

The Entity is not aware of any contingent liability or contingent asset.

13. Commitments

The Entity is committed to the contractual terms under its grant funding agreement with the Department of Health. There were no other commitments at 30 June 2019.

14. Events subsequent to balance date

On 8 July 2019, the Entity paid $745,250 to BioGrid Australia Limited as part of its service provider agreement with the supplier. There are no other material events subsequent to balance date.

15. Entity details

The registered office of the Entity is L7 The Kinghorn Cancer Centre, 370 Victoria Street, Darlinghurst NSW, 2010.

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 2019 and of its performance for the financial period ended on that date;

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

2. There are reasonable grounds to believe that AGCMC will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Board:

Mark Wainwright
Chair

Bruce Goodwin
Director

Sydney

4 October 2019

Grant Thornton

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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 2019, and the statement of profit or loss and other comprehensive income, statement of changes in funds and statement of cash flows from incorporation on 20 July 2018 to the period ending 30 June 2019 (the period), 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 Division 60 of the *Australian Charities and Not-for-profits Commission Act 2012 ("ACNC Act")*, including:

1. giving a true and fair view of the Registered Entity's financial position as at 30 June 2019 and of its financial performance for the period then ended; and
2. complying with Australian Accounting Standards and Division 60 of the *Australian Charities and Not-for-profits Commission Regulation 2013*.

Basis for opinion

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

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

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 and the ACNC Act, 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

James Winter
Partner – Audit & Assurance

Sydney, 4 October 2019