



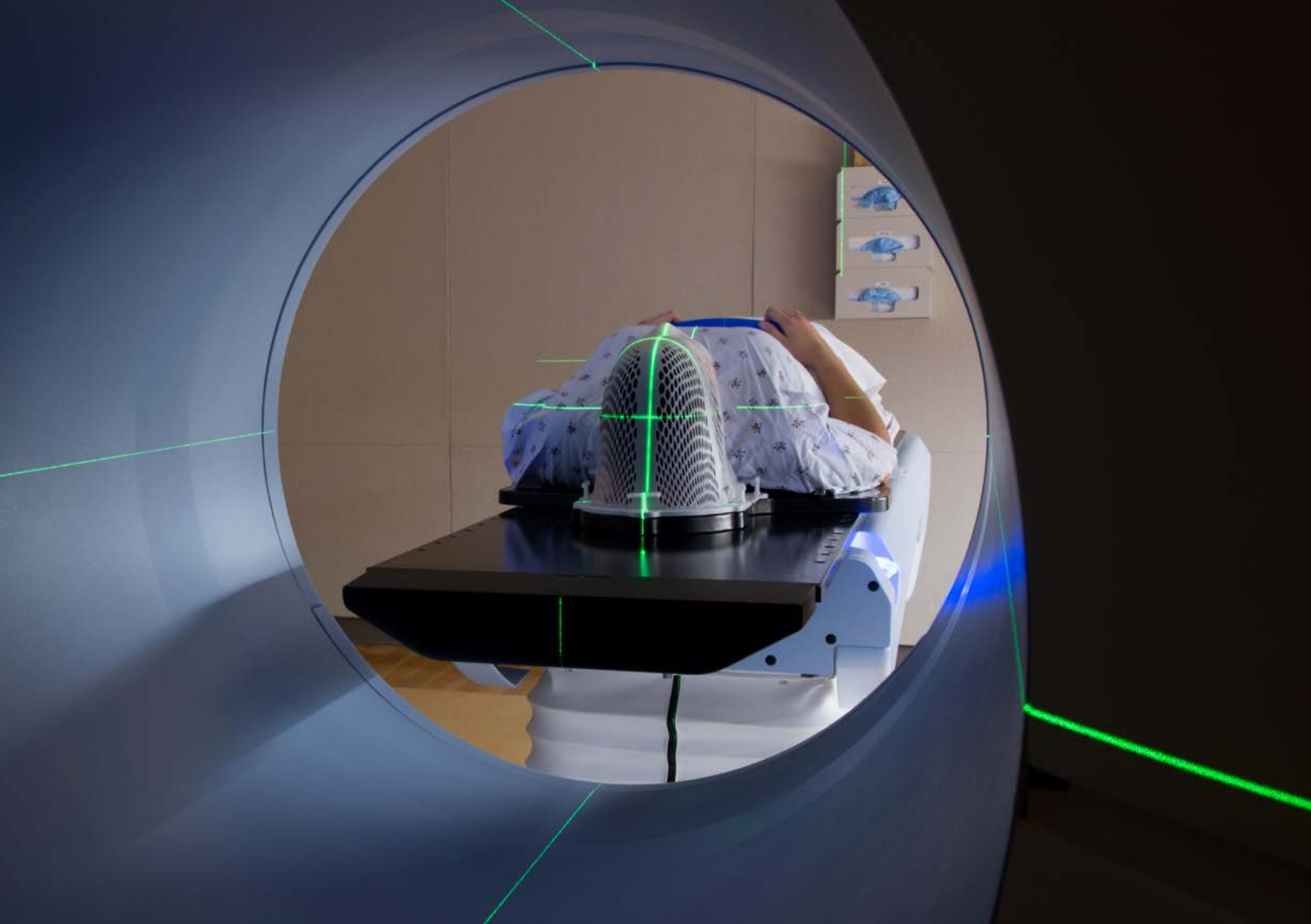
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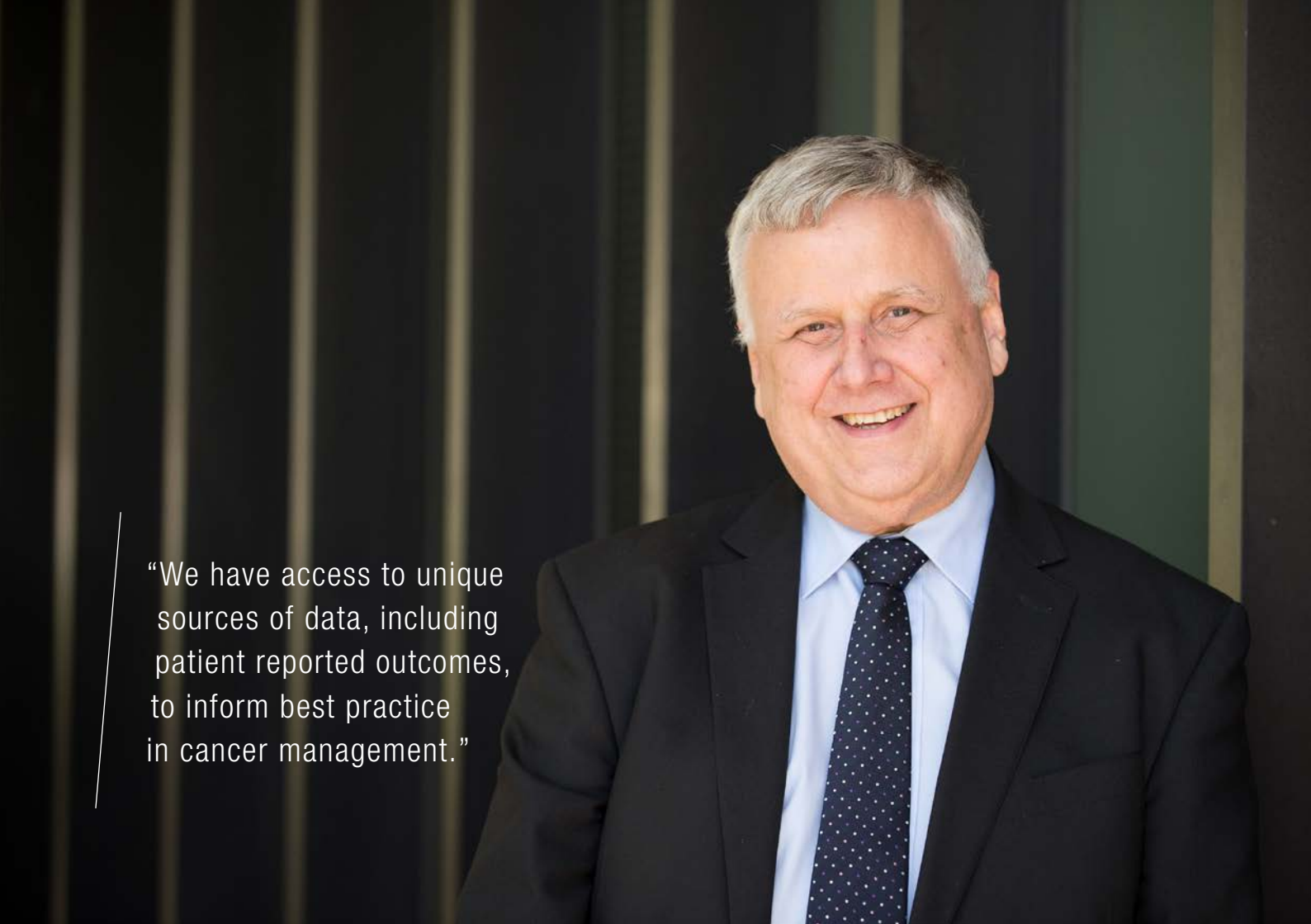
CANCER RESEARCH PORTFOLIO

MONASH
PUBLIC HEALTH AND
PREVENTIVE MEDICINE

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“We have access to unique sources of data, including patient reported outcomes, to inform best practice in cancer management.”

Foreword – Professor John McNeil

Melbourne's premier hub of population based cancer research

I am pleased to present the Cancer Research Portfolio for Monash Public Health & Preventive Medicine. It demonstrates the breadth of cancer research being undertaken amongst various units within the School.

As the Australian population ages, the burden of disease arising from cancer will grow. 134,000 new cases of cancer are expected to be diagnosed amongst Australians during the next 12 months and half the population will be diagnosed with cancer by the time they turn 85. At the same time cancer is an area of rapid advances posing considerable challenges for health systems to providing optimal care in an equitable manner.

Public Health and Preventive Medicine at Monash University is involved in research that aims to improve cancer diagnosis, treatment, care and outcomes. Our work extends from genomics and clinical trials to registries which benchmark the quality, safety and outcomes of clinical care. We have been amongst the leaders in introducing patient-reported outcome measures to guide clinical care.

We are fortunate in the range of collaborators and partners involved in our cancer research. They include the Peter McCallum Cancer Centre, the Garvan Institute in Sydney and the Icahn Institute in New York with its expertise in cancer genomics. Our work is funded from a range of leading institutions including the Movember Foundation and other charities, National Health and Medical Research Council, the US National Institutes of Health and a number of corporations.

Our facilities are expanding and we now occupy space in two buildings at the prestigious Alfred Medical Research and Education Precinct in Melbourne, Victoria. Our work is facilitated by access to some of the most valuable 'data-assets' including the ASPREE trial/cohort and our various clinical quality registries. We are rapidly expanding in the field of genomic research and our co-location with the Alfred Hospital, the Baker Institute and Burnet Institute creates additional collaborative opportunities that will underpin our research in the future.

I am impressed by the potential of our cancer research and the skills and achievements of those involved, particularly my colleague Professor John Zalcberg who leads cancer research in our School.

If you would like further information outside this booklet, please contact med-cancerregistries@monash.edu

Professor John McNeil

Head of School

“We have significant expertise in study design and management, making us attractive to funders who know they will see return on their valuable investments.”



Foreword – Professor John Zalcborg

Providing intelligence on cancer prevention, diagnosis, rates and treatments

I am proud to lead one of Australia's most trusted sources of high-quality cancer research.

Our expansive research portfolio includes randomised clinical trials, observational studies, cohort studies and qualitative investigation techniques to explore a variety of aspects of many cancer types. We have significant expertise in study design and management, making us attractive to funders who know they will see return on their valuable investments.

We are Australia's largest manager of clinical registries, and almost a third of our approximately 30 registries are related to cancer. These monitor variance in cancer care and outcomes, allowing service providers to benchmark their work and providing data for large epidemiological cancer studies. Our registry program continues to expand as new registries are added, pilot registries come to maturation and existing registries are cross-linked with external and internal registries and datasets.

Our bio-banks contribute molecular, morphological and histological data to future studies. Behind much of our work is a focus on translation that aims to generate practical policies and programs.

Our School collaborates with partners and funders across government, not-for-profit and industry, domestically and internationally. In these pages you'll find cancer research programs funded by groups as diverse as the United States Military, the Icahn Institute at Mt Sinai, NIH, NHMRC, Victorian Department of Health and Human Services, the Movember Foundation and a range of pharmaceutical companies.

The presence of distinguished researchers in social science research allows us to capture and analyse patient reported outcome measures. Our work also extends into cancer ethics, as we grapple with and investigate consequences arising from the return of incidental genetic findings discovered during medical research. This ensures our research is tailored to achieve findings that improve outcomes in holistic ways that all Australians truly value.

If you are interested in funding or research opportunities with us, please contact med-cancerregistries@monash.edu

Professor John Zalcborg
Head of Cancer Research

Introduction

We have research strengths across multiple clinical cancer domains, and in a variety of study designs and cutting edge data analysis techniques. These strengths are leveraged in all cancer research projects we undertake.

Our team have led numerous clinical cancer trials with significant global impact, including a major study to assess the impact of a novel drug for people with inoperable gastro-intestinal stromal tumours. This study was a major turning point in determining the role of a new drug for patients with these previously incurable tumours and changing the standard of care for patients.

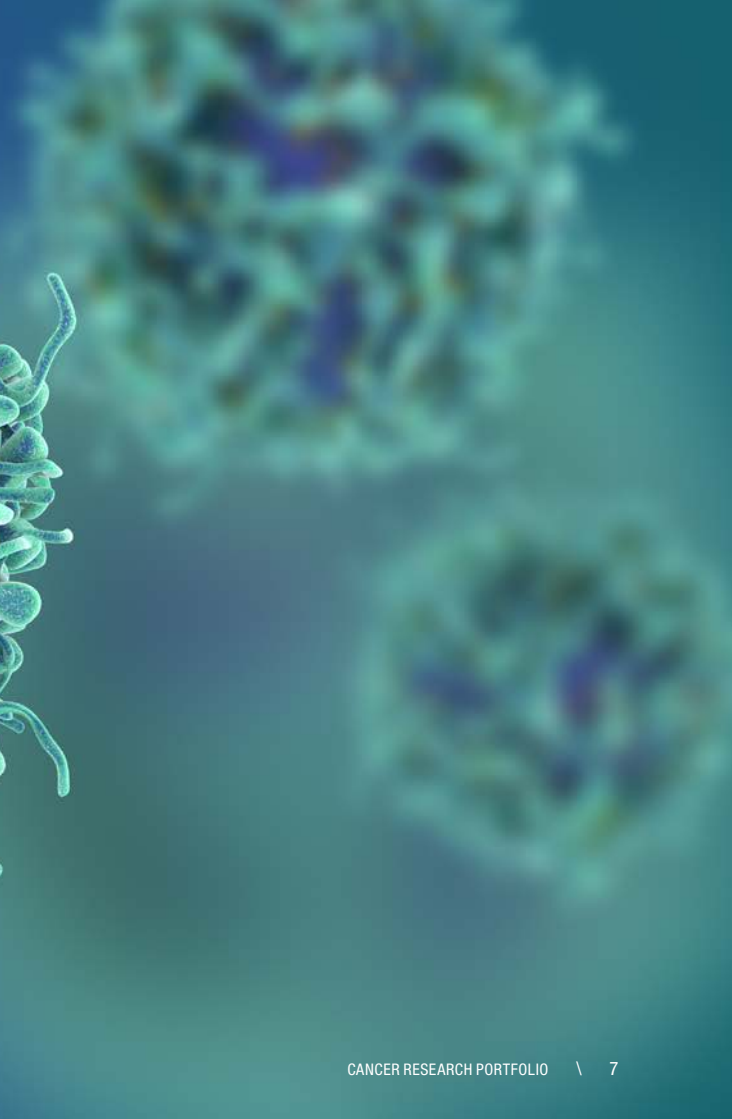
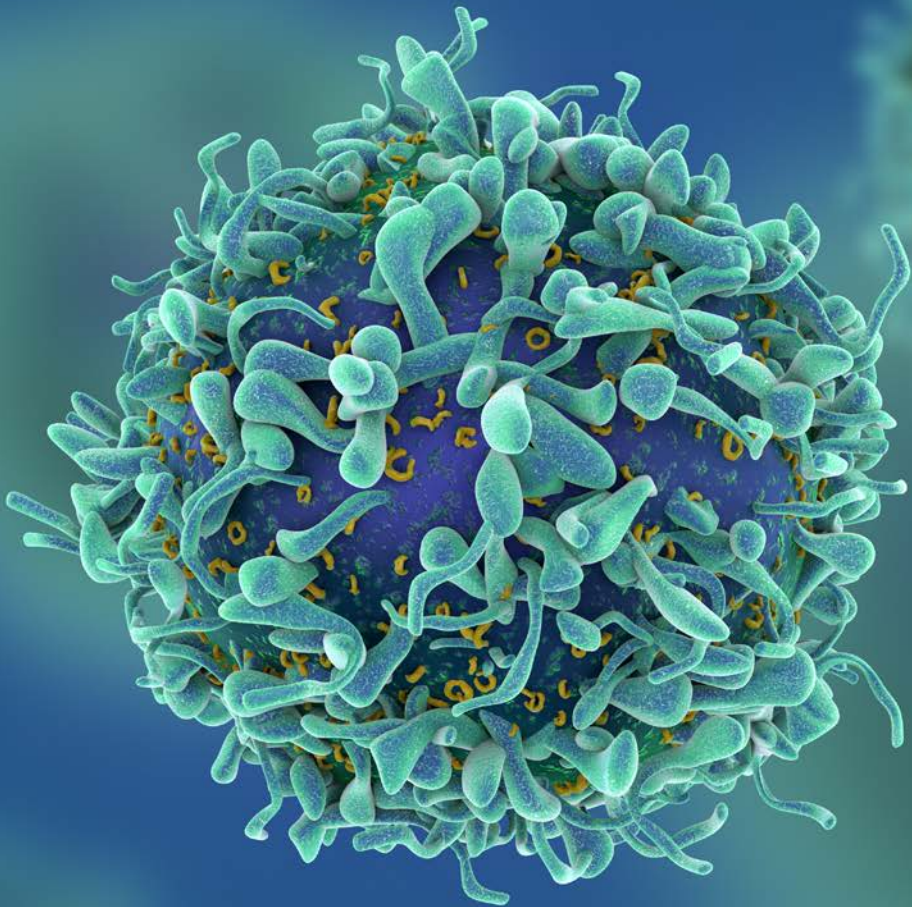
We are Australia's largest manager of clinical registries, with around ten cancer-related registries under our auspices. These provide important clinical quality benchmarking for cancer care, and research data across lung, prostate, thyroid, upper gastrointestinal, ovarian and blood cancers.

Our Genomics unit is investigating potential protective effects of aspirin against colorectal cancer and evaluating the roles of genetic predisposition and the environment in cancer genesis. We are also screening all ASPREE samples for known cancerous mutations, which will provide detailed prevalence and penetrance data.

Patient Reported Outcome Measures (PROMs) provide valuable information about patient experiences and accessibility of cancer care. Our Social Sciences team are pioneers in this area, conducting research into experiences of fertility preservation for people with cancer and the impact of prostate cancer care among men in regional Australia.

We are home to Cochrane Australia, the world's leader of evidence based reviews that inform health-related decision making. The group undertakes research into knowledge translation, advocates for evidence-based health policies and provides evidence consultancy services. Over 700 Cochrane reviews with relevance to cancer treatment and care are freely available to all Australians.

Our Occupational and Environmental Health team manage workplace epidemiology studies exploring cancer incidence among high-risk workers, including those in the aluminium, petroleum and fire-fighting industries.





Improving outcomes

The Prostate Cancer Outcomes Registry Victoria identified worse prostate cancer outcomes for men in Gippsland than for men in other areas of Victoria. The information provides an opportunity to investigate and improve.

Prostate cancer

Background

Prostate cancer is the most common cancer diagnosed in Australia. We manage two clinical registries which drive improvement in clinical care for this cancer, partnering with community groups including the Movember Foundation to achieve this.

Highlights

Cohort studies

- **Examining the interactions between General Practitioners and prostate cancer patients in the Gippsland area (TrueNTH):** A cohort study investigating reasons behind comparatively poor clinical outcomes for men in Victoria's Gippsland region.

Qualitative studies

- **Prostate cancer in regional, remote and metropolitan areas in Victoria and South Australia: Understanding the experiences and perspectives of patients, partners, men with no history of prostate cancer, Urologists, and General Practitioners to inform comprehensive care:** An investigation into the experiences of multiple prostate cancer stakeholders surrounding unmet needs and barriers to accessing healthcare.

Clinical registries

- **Prostate Cancer Outcomes Registry – Australia and NZ:** This registry monitors, assesses and evaluates patterns in quality of care and treatment outcomes for men diagnosed with prostate cancer based on clinical evidence-based guidelines.
- **Prostate Cancer Outcomes Global Initiative to Compare and Reduce Variation in Localised Cancer (PCO-CRV):** A study across 100 sites in 12 countries, aimed at measuring and evaluating clinical and patient reported physical and mental health outcomes in men treated for localised prostate cancer.

Lung cancer

Background

Lung cancer is the fifth most commonly diagnosed cancer type in Australia.

Highlights

Clinical trials

- **Phase Ib bioequivalence study of a radical dose of RT in lung cancer:** A trial to determine the maximum tolerated dose of radiotherapy for patients with Stage III/locally advanced NSCLC, using doses equivalent to palliative treatments and building up to doses equivalent to curative standard of care.

Clinical registries

- **Victorian Lung Cancer Registry:** Operating since 2011, the registry collects data from clinicians, health services, researchers and consumers that enables reports on clinical and patient-reported outcomes, and quality of care for Victorians recently diagnosed with non-mesothelioma lung cancers.

Gynaecological cancer

Background

It is estimated that over 6,000 cases of gynaecological cancer will be diagnosed in Australia in 2017. Some of these cancers have subtle symptoms, so prevention and early diagnosis are key.

Highlights

Clinical trials

- **Investigating the use of metformin for the prevention of endometrial cancer:** Explores metformin use in women with hormone receptor positive breast cancer being treated with tamoxifen.

Clinical registries

- **National Gynae-Oncology Registry (NGOR):** A multi-module gynaecological cancer registry, which will include the Ovarian Cancer Registry.



Patient-centred research

Our Social Sciences teams are experts in qualitative research methods and Patient Reported Outcome Measures exploring health service accessibility, equality and patient experiences during cancer treatment.



Driving quality

We are Australia's largest manager of clinical registries, with around ten cancer-related registries under our auspices.

These provide important clinical quality benchmarking for cancer care and research data across numerous cancer types.

Haematologic malignancies (Blood cancers)

Background

It is estimated that over 11,900 cases of lymphoma, leukaemia and myeloma will be diagnosed in 2017. We maintain a diverse portfolio of clinical trials and clinical registries relevant to blood cancers.

Highlights

Clinical trials

- **Trial to Evaluate Tranexamic Acid in Thrombocytopenia (TREATT):** International double-blinded RCT evaluating a low cost, antifibrinolytic agent (tranexamic acid) to prevent or treat bleeding in people with blood cancer and severely low platelet counts.
- **Role of Antibiotic Therapy or IVIg on Infections in Haematology (RATIONAL):** An Australian and New Zealand pilot/feasibility trial comparing oral antibiotics with immunoglobulins to prevent infection in adults with haematologic malignancies and low immunoglobulin levels.

Clinical registries

- **Myeloma and Related Diseases Registry (MRDR):** Stores treatment and outcome data to guide best-practice in clinical care and drive translation of emerging treatments such as targeted therapies.
- **Australian and New Zealand Lymphoma and Related Diseases Registry (LaDR):** Collects treatment and outcome data for lymphoma. Partners with Melbourne Genomic Health Alliance.

Bio-banks

- **M1000:** MRDR sub-study forming the world's only prospective, fully annotated liquid biopsy biobank for myeloma and monoclonal gammopathies of undetermined significance.

Gastrointestinal cancer

Background

We contribute to the important body of evidence about this group of cancers with relatively poor prognoses. In 2012, more than 12,000 people died of gastrointestinal cancers, more than twice the combined total for breast and prostate cancers.

Highlights

Cohort Studies

- **Optimising care for patients diagnosed with pancreatic cancer:** Prospective cohort study utilising data from the Upper Gastrointestinal Cancer Registry to improve the health outcomes of patients with pancreatic cancer by providing regular audit and feedback reports to clinicians and hospitals, benchmarking their performance on evidence-based care indicators and health outcomes against their peers.

Clinical registries

- **Upper Gastrointestinal Cancer Registry:** Monitors the quality of care and identifies gaps in service quality provided to Australians diagnosed with cancers of the oesophagus, stomach, liver, bile ducts and pancreas.

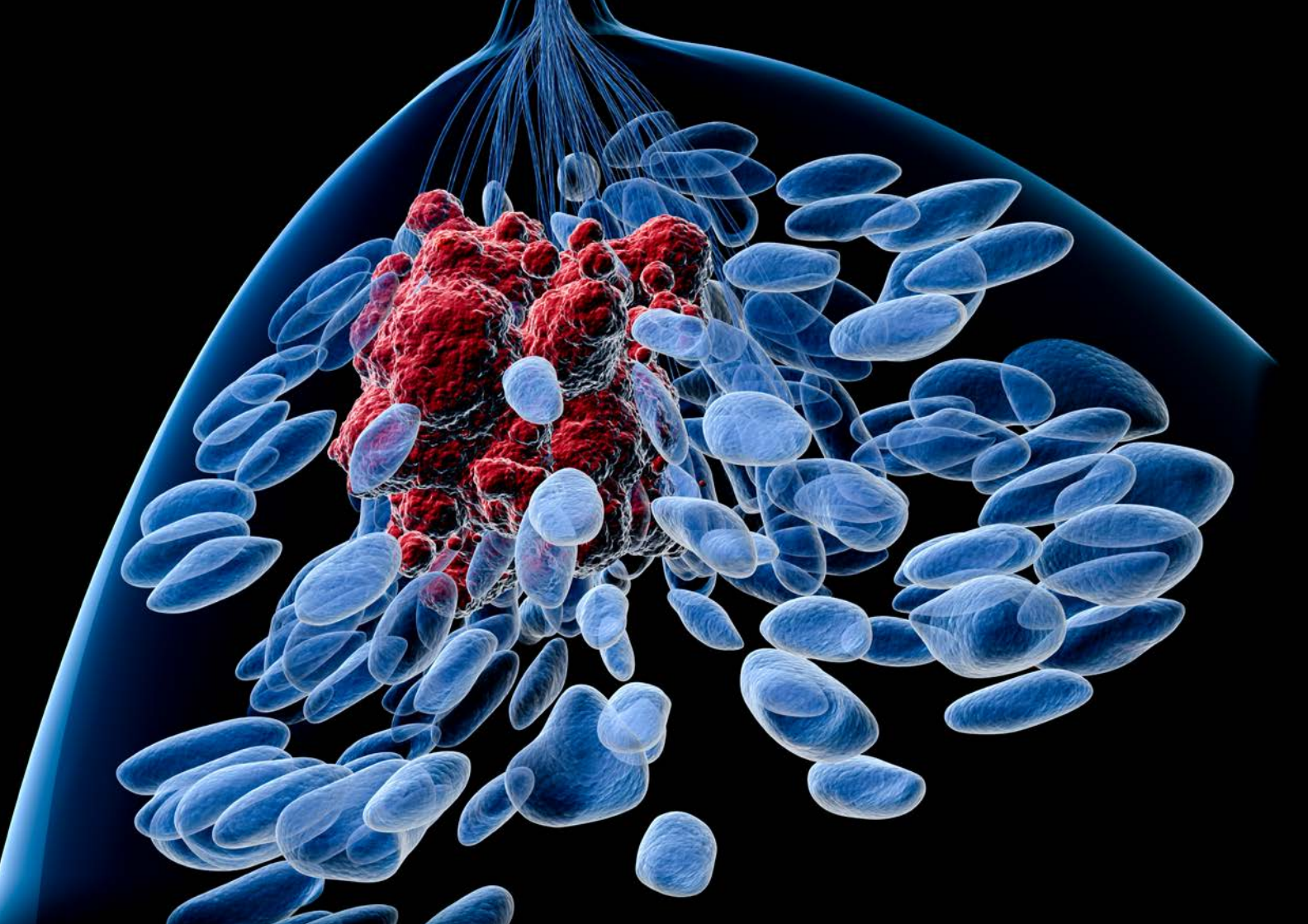
Biobank

- **Pancreatic Cancer FNA Biobank:** A biobank storing fine needle aspirates used for diagnosis of pancreatic cancer linked with upper gastrointestinal cancer registry.

Global collaborations

Our cancer projects involve numerous international collaborations with institutes such as UCLA, Icahn School of Medicine and the International Consortium for Health Outcomes Measurement.





Breast cancer

Background

The School has an impressive portfolio of clinical trials, clinical registries and qualitative studies to evaluate the psychosocial effects of breast cancer.

Highlights

Clinical trials

- **ATLAS Adjunct Tamoxifen Longer Against Shorter (5 years vs 10 years):** Having established reduction in recurrence and mortality after five years of Tamoxifen, this study has been extended to review participants at the 10-year mark. Our School recruited more participants than any other Australian site.

Qualitative studies

- **What matters to women diagnosed with breast cancer during their reproductive years?**
A qualitative investigation of fertility, reproductive health, heritability, and related psychosocial needs using a population-based sample.
- **Breast cancer and fertility: Contributing to General Practitioners' management and support of their patients:** Investigation of women's experiences of reproductive health care and oncology care.

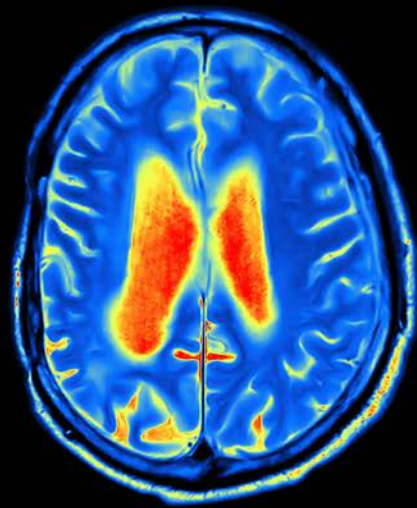
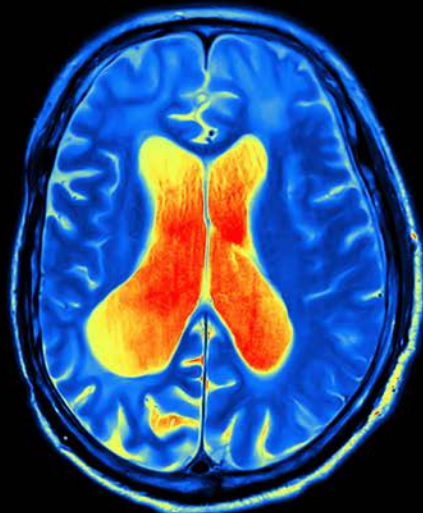
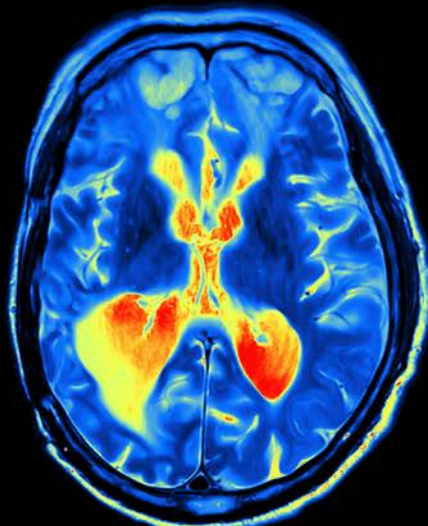
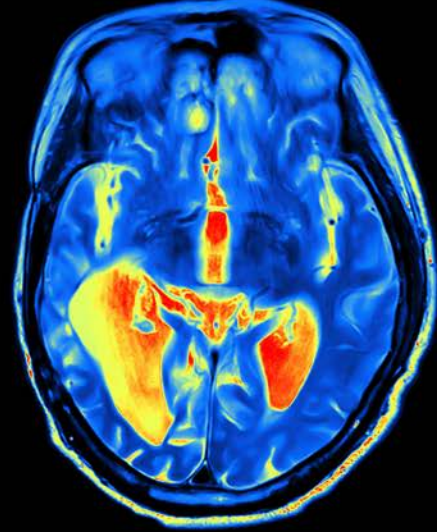
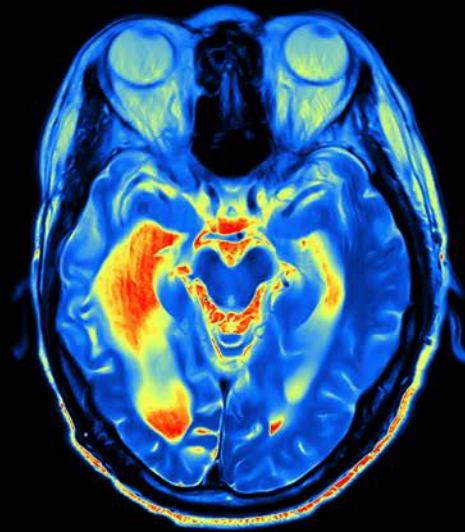
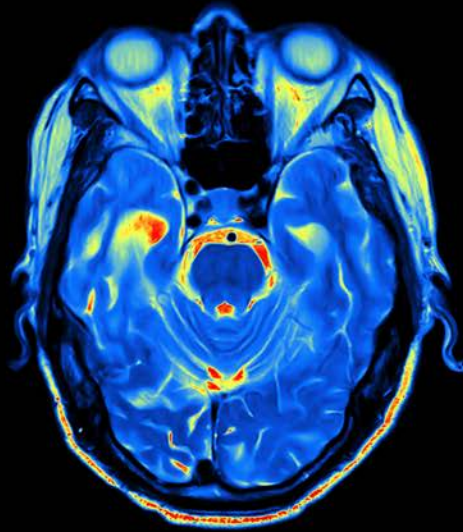
Clinical registries

- **Australian Breast Device Registry:** This tracks ongoing health outcomes of over 17,000 Australians with breast devices and implants, including women undergoing post-cancer breast reconstructions and risk reducing surgery. It will become increasingly important in tracking associations between textured implants and lymphoma.
- **Australian Breast Cancer Registry:** This new pilot registry will improve quality of breast cancer care by tracking diagnostic, histologic, molecular and treatment information. It will use novel data collection methods designed to increase registry cost-effectiveness.

Recruiting success

Our School is one of many trial sites for the US government funded ATLAS trial, looking at the benefits of long-term tamoxifen treatment for breast cancer. We recruited more participants than any other Australian site.







Brain tumours

Background

It is estimated that head and neck cancers will be the 18th leading cancer cause of death in Australia during 2017. We manage clinical trials and cohort studies exploring brain cancer.

Highlights

Clinical trials

- **StereoDex:** A double-blinded RCT evaluating efficacy of prophylactic dexamethasone when used with stereotactic radiotherapy in people with 1–3 brain metastases.

Cohort studies

- **MOBI-KIDS:** Case-control study involving 16 countries to investigate exposure to radiofrequency radiation from mobile phone use during childhood and adolescence and onset of brain tumours in people between the ages of 10 and 24 years.

Thyroid cancer

Background

Thyroid cancer is more common in women than in men. These cancers have a good prognosis, with the highest five-year survival rate of all cancers. Our thyroid cancer research reflects this in its focus on variance in outcomes and service provision.

Highlights

Clinical registries

- **Australian Thyroid Cancer Registry Pilot (ATCRP):** Pilot clinical quality registry designed to monitor diagnosis, treatment and early post-operative outcomes for people with thyroid cancer at contributing hospitals in Australia.

Leading the world

We manage the industry-funded M1000, the world's only prospective, fully annotated liquid biopsy biobank for myeloma and monoclonal gammopathies of undetermined significance.



Building for the future

We house multiple biobanks for use in cancer research. These could power studies to identify hereditary cancer risks, protective factors and inform personalised medicine.

ASPREE

Background

Aspirin in Reducing Events in the Elderly (ASPREE) is the world's largest primary prevention study exploring the protective effects of aspirin on ageing. The study's endpoints include cancer and together with the wealth of biochemical, biometric and lifestyle information collected, an associated biobank will facilitate future cancer studies.

Highlights

Clinical trials

- **Aspirin in Reducing Events in the Elderly (ASPREE):** Information has been collected from more than 16,700 healthy older Australians at multiple timepoints. Cancer diagnosis is a secondary outcome for all participants in the world's largest primary prevention study in healthy older people.

Cohort studies

- **ASPREE Cancer Extension Study (ACES):** An ASPREE sub-study determining if low-dose aspirin is protective against common malignancies. It includes phenotypic clinical information and a collection of tumour and saliva samples.

Bio-banks

- **Healthy Ageing Biobank:** Contains urine and blood samples from over 12,200 participants. For around 10,000 participants this includes baseline and three-year follow-up samples.
- **ASPREE Cancer Endpoint Study (ACES):** A saliva and tumour bank associated with the ACES sub-study. This contains nearly 700 tumour samples along with phenotypic data and approximately 1,750 saliva samples.

High-risk cohorts

Background

Long-term exposure to hazardous chemicals may increase the risk of cancers among some cohorts. Our School houses the Monash Centre for Occupational and Environmental Health, which runs numerous studies exploring cancer incidence among high-risk workers and community groups.

Highlights

Cohort studies

- **Leukaemia and benzene exposure:** Pooled analysis for three case control studies involving petroleum industry workers in Canada, United Kingdom and Australia.
- **Health Watch Study:** A long-term cohort study of Australian petroleum industry workers, established in 1981, to monitor cancer and mortality in workers in this industry.
- **Health Wise study:** This is a long term cohort study of Australian aluminium industry workers, which was established in 1993 to monitor respiratory disease, cancer and mortality in workers in this industry.
- **Australian Fire Fighters Study:** This is a long term cohort study of Australian employed and volunteer firefighters to monitor cancer and mortality in workers in this industry. Established in 2010 following reports from overseas of high cancer incidence in this cohort.
- **Hazelwood Mine Fire Study:** This 20-year study is investigating a wide range of health outcomes in the community adjacent to the Hazelwood Mine Fire in 2014, including cancer outcomes. Funded by the Victorian Government.



Translation in action

Our research has identified a novel myelodysplastic syndrome in workers exposed to petroleum. New safety measures have now been incorporated into guidelines to protect workers.



Innovation in ethical conduct

Our genomics team are developing ethical guidelines around the return of genetic information to participants in the ASPREE project, including results that may influence risk of cancer.

Other cancer research

Background

By 2020, an estimated 150,000 cases of cancer will be diagnosed each year, with one in two Australians diagnosed with cancer by age 85. It is the leading cause of death in Australia.

Sixteen general cancer projects are housed with the School, including clinical trials, cohort studies, clinical registries and bio-banks. These explore incidence, treatments, outcomes and impact of cancers of any aetiology.

Highlights

Clinical trials

- **STATins in Reducing Events in the Elderly (STAREE):** Clinical trial on the effects of statins on healthy ageing. A secondary outcome is determining correlations between statins and the timeframe of fatal and non-fatal cancers.

Cohort studies

- **Resilience Project:** International effort with New York's Icahn School of Medicine to identify rare individuals carrying damaging genetic variants who remain protected against the usual signs and symptoms of disease well beyond the expected age of onset. This includes sequencing of all ASPREE samples.
- **Are metal-on-metal hip replacements associated with an increased cancer risk?** Australian cohort study reviewing potential cancer risk in patients undergoing total hip replacements. This risk may arise from increased serum metal ions.

Collaborations

We collaborate with renowned domestic and international organisations. These relationships expand our research capacity and drive innovation by facilitating exchange of expertise with important research groups.

We partner with Cancer Council Victoria and the Victorian Department of Health and Human Services to manage clinical registries that provide benchmarking for cancer care and create a wealth of cancer data for epidemiological studies. For example, our Head of School, Professor John McNeil, chaired a Victorian Department of Health and Human Services led inquiry into a potential cancer cluster in the Victorian State Parliament building.

Cancer 2015 is a unique partnership with the Victorian Comprehensive Cancer Centre and other health services to drive targeted gene therapies for solid tumours. Our significant contribution includes registry design and management and major data infrastructure support.

We are the lead institute for the ASPREE study, the world's largest primary prevention aspirin study undertaken in healthy older people. Funded by the USA's National Cancer Institute, we collaborate with the Berman Center for Outcomes and Clinical Research to administer the project. The ASPREE study has numerous cancer-related sub-studies and the data collected provides enormous cancer research opportunities.

We are providing Sydney's Garvan Institute with thousands of ASPREE samples for whole genome sequencing to help distinguish pathogenic mutations from standard population variations.

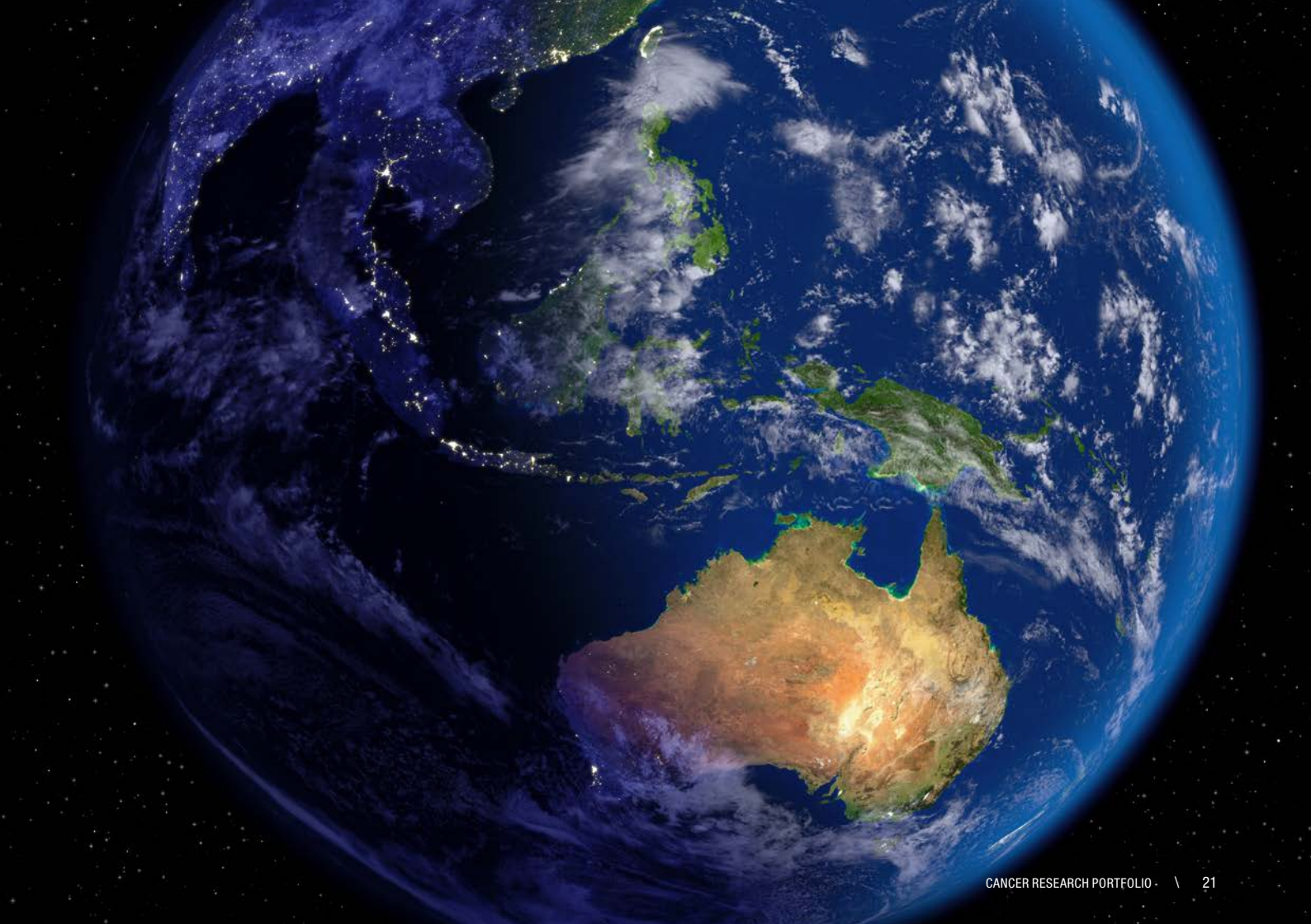
We work with New York's Icahn School of Medicine, Mt Sinai, on the Resilience Project, a search for genes that confer genetic resilience in healthy people carrying known disease-causing mutations.

Finally, our researchers have worked with the International Consortium for Health Outcomes Measurement to develop global standard sets for colorectal cancer indicators and localised and advanced prostate cancer. Our team serves as the data coordinators for the Global Prostate Cancer Registry, collaborating closely with project coordinators at UCLA.

Funding agencies

We would like to acknowledge the following funding organisations, without which these projects would not be possible:

Abbvie	Eli Lilly Australia	NSW state government (OHMS)
Alcoa of Australia	GSK	NVS
Amgen	Icahn Institute (USA)	Onyx
Ariad	Janssen	Ovarian Cancer Australia
AstraZeneca	Juniper	Pancare
Australasian Fire & Emergency Service	Maddie Riewoldt's Vision	Phebra
Authorities Council	Merck	Prostate Cancer Foundation of Australia
Australian & New Zealand Society of Blood Transfusion	Monash Health	Roche
Australian Institute of Petroleum	Monash Partners Academic Health Science Centre	Safe Work Australia
Australian New Zealand Endocrine Surgeons	Movember Foundation	Shire Australia
Australian Rheumatology Association	National Institutes of Health (USA)	STA
Bristol-Myers Squibb	National Blood Authority	Takeda
Cancer Australia	National Breast Cancer Foundation	US military
Contributing to Australian Scholarship and Science (CASS) Foundation	National Health and Medical Research Foundation	Victorian Cancer Agency
Celgen	National Cancer Institute (USA)	Victorian Department of Health and Human Services
Conservation of Clean Air and Water in Europe	NHS Blood & Transplant (UK)	Volpara
Commonwealth Scientific and Industrial Research Organisation	Novartis	





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