ST VINCENT'S HEALTH AUSTRALIA

UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES

2023 SVHA Research Report

Clinical Trials: Advancing clinical care through research

St Vincent's Health Australia

Our Mission

As a Catholic healthcare service we bring God's love to those in need through the healing ministry of Jesus. We are especially committed to people who are poor or vulnerable.

Our Values

COMPASSION

INTEGRITY

JUSTICE

EXCELLENCE

Contents

"This Report is a glimpse of the many aspects of St Vincent's research over the past year, and I commend it to you all."

Mr Paul McClintock AO, Chair

Introduction

Mr Paul McClintock AO

Chair, St Vincent's Health Australia
Group of Companies

St Vincent's 2023 Research Report showcases the extraordinary range of research carried out within our organization nationally, and in our affiliated institutes, with a focus this year on the central role of clinical trials.

I welcome this focus as it is the pathway through which crucial basic research makes its way to the bedside of our patients, with its life-giving impact. That pathway is often overlooked with fewer high-profile stories, but it stands side by side with basic research as an equal partner. It is also an area where the pace of change has been hectic in recent times.

I had the honour recently of speaking at the retirement from his St Vincent's research leadership role of Professor Terry Campbell AM, one of our truly great researchers, and research leaders. In those remarks I described concentric circles of impact from research leadership, spreading out like ripples in a pond. The first two circles will be easily recognized by all who read this Report, but the third perhaps less so.

The first circle covers those directly impacted by an individual's research, particularly across their own clinical practice. These people we can see, they are identified, and they are grateful. That impact is often acute, and powerful enough to support the sacrifice research always requires. The second circle are those impacted by others, as a research leader touches so many others with their own developing circles – mentoring, encouraging, helping with funding, motivating what can be a lonely path. Have no doubt such leaders have a powerful impact well beyond what we, or they, can measure – and that impact lasts well after they have retired.

Whilst those two circles are familiar, for those responsible for St Vincent's the ripples do not stop there – there is a crucial third circle which is the impact on St Vincent's itself. St Vincent's is Australia's largest NFP health organization, with around 30,000 people working for or with us, with over 3.5 million patient interactions every year.

It is the core legacy of the wonderful Sisters of Charity. Yet its role is challenged, sometimes noisily in public forums or more often quietly and gradually in underfunding essential expenditure. This means we all need to showcase better what makes St Vincent's important to our society – something to be valued and nurtured.

Which takes us directly to research, and to clinical trials, as no description of St Vincent's is complete without its extraordinary research footprint as a key pillar, with our commitment to see the genius of our researchers, and that of others, tested in our facilities through trials that can bring the very best chance of recovery to all our patients. It is part of the glue which holds us together, and its strength is a hallmark of St Vincent's. It is the third circle of impact.

This Report is a glimpse of the many aspects of St Vincent's research over the past year, and I commend it to you all. It is where the spirit of innovation, and risk taking for others, of the original Sisters lives out today.

The Board would like to express our deep gratitude to all of you – researchers, clinicians, philanthropists and so many others - who contribute to making our research such a powerful part of who we are today.

Mr Paul McClintock AO,
Chair, St Vincent's Health Australia
Group of Companies

Mr Chris Blake

CEO, St Vincent's Health Australia Group of Companies

Health and aged care are on the threshold of unprecedented and fast-paced transformation.

And while we're confident in a number of ways that change will take place – faster and more convenient care in people's homes thanks to rapidly improving technology; hospitals operating as 'health hubs' delivering virtual and home services in the community; advances in genomics, immunology, and imaging fulfilling the enormous promise of precision health – there is much we don't know.

Research is key to unlocking healthcare's possible future and taking us over the threshold.

Across our hospitals and co-located institutes, the St Vincent's research footprint is one of the biggest in Australia with 2,500 people, 3,000 annual publications, and $285 million in annual income.

Medical research has always been core to St Vincent's and has reflected the pioneering spirit of our organisation.

The St Vincent's Institute of Medical Research began more than 60 years ago and produced the world's first machine that could speed up and automate the sequencing of proteins, affectionately known as 'The Sequenator'.

It was the Sisters of Charity and St Vincent's who established the Victor Chang Cardiac Research Institute.

The Garvan Institute of Medical Research began its existence as a small research department at St Vincent's Sydney.

The Kirby Institute began as the National Centre for HIV Epidemiology and Clinical Research by the late St Vincent's clinician, Professor David Cooper AC.

The Aikenhead Centre for Medical Discovery – Australia's first collaborative, hospital-based biomedical engineering research centre – is currently being built on the grounds of our Melbourne campus.

The St Vincent's family of research institutes – some of them household names – have unlocked our healthcare future on numerous occasions in the past.

Now, as we enter a new era of discovery, where the time between medical breakthrough and its bedside application will become shorter and shorter, research conducted by St Vincent's clinicians and our partners will do so again, continuing to transform our hospitals and the way we provide our care and treatment.

This year's research report is testament to the appetite for innovation and invention that will always be part of the St Vincent' story.

Mr Chris Blake,
Group Chief Executive Officer,
St Vincent's Health Australia

"Research is key to unlocking healthcare's possible future and taking us over the threshold."

Mr Chris Blake, CEO

SVHA Research

SVHA Research has been envisaged as a centralised resource to facilitate and align the national approach to research across the organisation.

Our aim is to build an SVHA-wide research community that drives excellence in care and champions our organisation's vision and values.

SVHA Research aims to:

> Facilitate research governance, organisational policy, and process development

> Connect with researchers, clinicians and leaders spanning all SVHA divisions and institutes

> Share knowledge about the research activities and resources available across SVHA

> Facilitate opportunities for engagement and collaboration, both within and outside of SVHA

As the facilitator of the SVHA-wide research community, SVHA Research will be responsible for implementing the organisation-wide Research Strategy, 'Our Life Changing Research'.

SVHA Research Milestones (FY 2022-2023)

Since the launch of the 'Our Life-Changing Research', SVHA Research has been actively building relationships across the St Vincent's research community and strengthening our existing research portfolio through several important initiatives. Key achievements and milestones from the past financial year include the following.

Dr Stacey Panozzo (on screen, left), Research Fellow, Palliative Nexus Research Group, University of Melbourne, and St Vincent's Hospital Melbourne

Dr Davinia Seah (right), palliative care staff specialist, Sacred Heart Health Service & St Vincent's Hospital Sydney

2022 SVHA Research Symposium

The SVHA Research Symposium showcases research across the SVHA organisation, promotes collaboration within and between craft groups across the facilities and highlights opportunities for SVHA to support key research themes.

For the first time, the SVHA Research Symposium was hosted as a hybrid event on Tuesday 8 November 2022 at the St Vincent's Applied Medical Research Centre in Sydney and online. It was well attended by members across the St Vincent's organisation, including Board members, Group executives, facility executives, researchers, and other stakeholders.

The Symposium featured a collaborative morning session on **Palliative Care** research with a focus on health services research, innovative therapies and presenting a vision to promote St Vincent's as a leader for evidence-based End-of-Life care. This was followed by an engaging Plenary session, **'Optimising Collaborations across Organisations: Barriers and Opportunities'**, which included presentations from **Professor Sharon Lewin** (Peter Doherty Institute for Infectious Diseases and Immunity), **Professor John Prins** (Health Translation Queensland) and **Dr Pete Ayre** (CardioBionic Pty Ltd). Comprehensive afternoon sessions featured cutting-edge **Haematology** research including myeloma trials and translational research from 'Bench to Bedside'.

A SVHA Research Dinner was hosted on Monday 7th November 2022 to celebrate the Palliative Care and Haematology researchers presenting at the Symposium and provide an opportunity for the Board to engage with these researchers.

"Medical research has always been core to St Vincent's and has reflected the pioneering spirit of our organisation. "

Mr Chris Blake, CEO

Plenary - Think Big: Future Directions in Digital Health.
From left: Michelle Fitzgerald, Dr Ian Oppermann, Dr Stefan Harrer and Associate Professor Michael Coote.

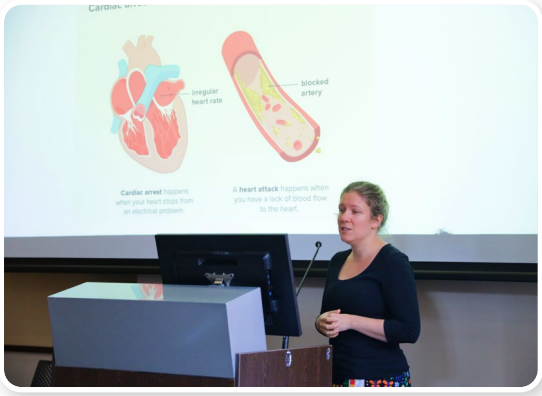
2023 SVHA Research Symposium

The 2023 SVHA Research Symposium was hosted as a hybrid event on Monday 1st and Tuesday 2nd May 2023 at the Education and Learning Centre, St Vincent's Hospital Melbourne. Spread across two days, the Research Symposium celebrated **Gastroenterology & Hepatology** and **Cardiology** research across St Vincent's and featured two 'Think Big' Plenary sessions from leading experts in digital health and cultural diversity.

The first day of the Research Symposium opened with a Plenary session, **'Think Big: Future Directions in Digital Health'**, which featured exciting talks about Digital Innovation from **Dr Stefan Harrer** (Digital Health Cooperative Research Centre), **Dr Ian Oppermann** (NSW Government) and **Ms Michelle Fitzgerald** (St Vincent's Health Australia). This was followed by two engaging **Gastroenterology & Hepatology** sessions that highlighted the current scope of research across luminal gastroenterology complications, inflammatory bowel disease, Hepatitis B and C diseases and Hepatocellular carcinoma.

"We thank all researchers, presenters, and organisers across the 2022 and 2023 Research Symposiums for their time and support in making both Research Symposiums a success."

Dr Craig Haifer, Gastroenterologist, St Vincent's Hospital Sydney



Dr Elizabeth Paratz, Cardiologist, St Vincent's Hospital Melbourne

Plenary – Think Big: Engaging with Culturally and Linguistically Diverse Communities in Aged Care Research.

Professor Bianca Brijnath.

The morning of the second day opened with two **Cardiology** sessions, which featured a presentation on the overall vision and future directions of Victor Chang Cardiac Research Institute. These dynamic sessions also covered a diverse range of research across Cardiology including the impact of exercise on blood pressure and cardiac-related complications during chemotherapy, genetics and the heart, cardiac diseases in systemic sclerosis and building a big data approach to screen cardiac arrests.

The Symposium concluded with the second Plenary session, **'Think Big: Engaging with Culturally and Linguistically Diverse Communities in Aged Care Research'**, where **Professor Bianca Brijnath** (Divisional Director of Social Gerontology at the National Ageing Research Institute) spoke about how to encourage participation of culturally and linguistically diverse communities to participate in clinical research. This includes Professor Brijnath's current initiative, 'Moving Pictures', which seeks to disseminate culturally appropriate information to potential participants via films, comics, and websites.

A SVHA Research Dinner was held between both days to thank researchers across Gastroenterology & Hepatology and Cardiology themes, and to promote engagement between our researchers and the Board.

We thank all researchers, presenters, and organisers across the 2022 and 2023 Research Symposiums for their time and support in making both Research Symposiums a success.

St Vincent's 2023 'Have Your Say' Survey – Research

During May 2023, all staff across St Vincent's received another opportunity to '**Have Your Say**' on the current working environment at St Vincent's.

Running for the second year, '**Have Your Say**' is a single consolidated employee survey on engagement, safety, organisational culture, and research. SVHA Research was given the opportunity to include four questions that assessed the number of staff actively involved in research, the perception of organisational support relating to research, and how staff view the research activities at SVHA.

The survey was promoted for two weeks in May, and **40%** of employees responded to the survey – a 5% increase from the previous year.

Compared to the 2022 survey, below are the general perceptions of research at St Vincent's among our workforce:

> The percentage of respondents supportive or interested in research remain the same as the 2022 survey (**55%**). There has been a **2%** increase in the percentage of SVHA employees actively involved in research (**20%**).

> **38%** of employees believe that St Vincent's support its staff to be involved in research, which is a 4% increase from the previous year.

> Almost two-thirds (**61%**) of employees believe that St Vincent's participates in important clinical research, a 5% increase from the previous year.

> **57%** of employees stated that they are proud of the research undertaken at St Vincent's, a 5% increase from the previous year.

National Clinical Trials Governance Framework

The National Clinical Trial Governance Framework (NCTGF) has been established by the Australian Commission on Safety and Quality in Health Care and will become a formal part of the NSQHS Standards from 2026 that is applicable to all health services undertaking interventional clinical trials. This framework supports the integration of clinical trial service provision into routine hospital care for improved patient outcomes.

Assessments for the NCTGF have commenced across Australia on the May 1st, 2023, and scoring will be based on a maturity scale (Established, Growing or Initial systems in place). SVHA Research will continue to work the public hospitals that have already participated in the NCTGF Pilot program in 2020/2021 and will provide education and support to the private facilities. This includes developing a central repository of documents to support all St Vincent's facilities involved in NCTGF accreditation.

SVHA Research Themes

SVHA Research Themes bring together researchers in similar clinical areas across SVHA to coordinate research activity, promote collaboration across the organisation, and strengthen our St Vincent's research identity.

Cardiology is being developed as the second multi-disciplinary central research theme at St Vincent's. This initiative is currently being facilitated by Professor Jason Kovacic (Executive Director) via the Victor Chang Cardiac Research Institute expansion plans by linking to St Vincent's cardiologists across all states.

In addition to Cardiology, Dr Chris Jacobs-Vandegeer (Group Mission Lead) is leading the development of a **Health Equity Research Hub** at St Vincent's, which is designed to improve health equity in Australia and internationally through innovative research, translation, and advocacy.

As featured in the 2022 SVHA Research Report, **Palliative Care** continues to be an important central research theme for St Vincent's. The SVHA Palliative Care Research Working Group continues to meet to collaborate and develop feasible research projects to establish SVHA as a leader in evidence-based End-of-Life care research.

Our Life Changing Research

'**Our Life Changing Research**' is our organisation-wide Research Strategy that builds on our strong commitment to health and medical research. The strategy frames SVHA as a research-rich organisation and promotes the SVHA goal to be a globally recognised leader in generating and implementing evidence into clinical practice. '**Our Life Changing Research**' is a five-year strategy, whereby the first two years will focus on establishing a SVHA-wide research community, and a well-recognised identity for SVHA Research.

Central to the strategy is positioning '**Better Care**' and '**Better Careers**' as key pillars, through three main areas of activity – **Capability**, **Collaboration** and **Connectivity**.

CAPABLE

Developing our leadership, talent, systems and funding sources

Activities

> Undertake an **organisational census** of research capability including personnel, activities, systems, employment models and supports to inform ongoing strategy development

> Develop a **framework** to support research activity in private and care services divisions

> Develop and implement a suite of **SVHA Research policies and procedures** to align processes and support NCTGF requirements

> Develop and implement a suite of **research KPIs** for reporting to the Executive and Board and for showcasing to potential partners and sponsors

> Develop a **SVHA Research strategy for clinical trials**, including creating a single comprehensive clinical trial identity and service nationally, and implementing a clinical trials management system

> Implement a **national ethics/governance program** to align and streamline ethics processes

> Explore **sustainable financial models** to enable research continuity and growth

COLLABORATIVE

Working together to optimise research quality, output and impact

Activities

> Establish **central research groups** to facilitate and coordinate activity across key research themes

> Develop and implement a national strategy for optimising commercialisation of research outcomes, including a **commercialisation framework** and standardised **IP policy and procedure**

> Develop and implement an **SVHA Research consumer engagement policy**

> Engage with our **philanthropic community** to explore potential models for research support based on an organisational approach

CONNECTED

Linking researchers, clinicians, consumers, partners and funders to build a high performing, research-oriented organisation

Activities

> Establish a **portal/website** for SVHA Research with content, functions and linkages relevant to target audiences including researchers, clinicians, consumers, sponsors etc.

> Conduct **research engagement surveys** for staff, participants and consumers more generally to inform ongoing engagement strategies

> Develop and implement a **communication and engagement strategy** for SVHA Research to support the objectives of the Strategy, promote organisation-wide awareness and engagement, promote the profile of organisation's research achievements and advocate for health and medical research

> Establish a **combined SVHA Annual Symposium** to showcase research and encourage cross collaboration

> Publish an **Annual Research Report**, including nationally KPIs and national recognition

> Promote **cross campus** research forums, staff development and opportunities

Research Snapshots

St Vincent's Melbourne partnering to drive innovation in diabetes management

Professor Richard MacIsaac

PROFESSOR RICHARD MACISAAC

Director of Endocrinology, Department of Endocrinology and Diabetes, St Vincent's Hospital Melbourne

PROFESSOR THOMAS KAY

Director, St Vincent's Institute of Medical Research

Diabetes is a key focus for research at St Vincent's Hospital Melbourne as we endeavour to address the growing health burden associated with this condition, which affects almost 1.9 million Australians and results in more than 1.2 million hospitalisations annually.

Led by Professor Richard MacIsaac, the Endocrinology and Diabetes Department at St Vincent's Hospital Melbourne collaborates widely on a range of investigator-initiated and sponsored clinical trials aimed at improving pharmacological management and outcomes for people with diabetes, working closely with fellow researchers in diabetes technology lead by Professor David O'Neal.

"We are involved in a broad range of trials, mainly in relation to type 2 diabetes as we seek to apply new medicines and technologies to improve glycaemic control and outcomes, particularly in relation to cardiovascular and renal complications" says Professor MacIsaac, who has led the unit for over ten years and is a Senior Principal Research Associate at St Vincent's Institute of Medical Research (SVI).

Recently, through their connections with researchers at the SVI, the clinical trials team has turned their attention to type 1 diabetes with their involvement in a potentially ground-breaking study investigating the role of immunotherapy in reducing the progression of the condition for newly diagnosed patients.

The multi-centre randomised placebo-controlled BANDIT (Baricitinib in new-onset type 1 diabetes) trial is a culmination of decades of research by SVI's Professor Thomas Kay and Professor Helen Thomas into the immune responses that lead to the development of type 1 diabetes and potential targets for therapeutic intervention.

"A diagnosis of type 1 diabetes is life-changing," says Professor Kay, who is strongly motivated by the impact of the condition on young lives and the limited therapeutic options available following a diagnosis, driving a career-long commitment to changing the trajectory of the disease. "By intervening early in the autoimmune process, we aim to limit damage, preserve cell function, and reduce the reliance on exogenous insulin. It is a potential game-changer for these patients."

A Janus kinase (JAK) inhibitor, baricitinib, belongs to a class of drugs successfully utilised in other autoimmune diseases such as rheumatoid arthritis and has shown promise in animal models for type 1 diabetes. The BANDIT trial sees the first clinical application of this drug in type 1 diabetes.

"It is an emotional and complex journey for people when they are first diagnosed with type 1 diabetes," reflects trial coordinator and diabetes educator Elizabeth Mulrooney, "so to be part of this trial has been both challenging and rewarding."

The enthusiasm for their clinical trial program is unmistakable among the St Vincent's team as they embrace the opportunities to advance clinical care and share a vision for significant steps forward in diabetes management.

Professor Thomas Kay

"Diabetes is a key focus for research at St Vincent's as we endeavour to address the growing health burden associated with this condition, which affects almost 1.9 million Australians and results in more than 1.2 million hospitalisations annually."

Step by Step to improve prostate cancer management and outcomes

Professor Louise Emmett

PROFESSOR LOUISE EMMETT

Director of Theranostics and Nuclear Medicine, St Vincent's Hospital Sydney and Clinical Research Leader of Advanced Prostate Cancer Group, Garvan Institute of Medical Research

In the rapidly developing field of Theranostics, Professor Louise Emmett and her team at Theranostics and Nuclear Medicine, St Vincent's Hospital Network Sydney are helping to pave the way through clinical trials that bring a targeted and personalised approach to cancer treatment.

Theranostics, combines therapy (thera) and diagnostics (ostics) to identify and target cancer cells for more effective treatment, while limiting damage to surrounding healthy tissue. The approach uses positron emission tomography (PET) imaging to identify specific tumour receptors, which in turn can be targeted by molecules carrying radioactive drug therapy.

"The science in this area has really accelerated our clinical capability", says Professor Emmett, remarking on the ground-breaking work that has resulted in significant improvements in the diagnosis, staging and treatment of prostate cancer over the past 10 years.

This success is evident in the major multi-centre PRIMARY trial series involving St Vincent's Hospital Network Sydney, St Vincent's Clinic, the Garvan Institute of Medical Research, Royal Brisbane and Women's Hospital, Brisbane and the Peter MacCallum Cancer Centre, Melbourne.

"Theranostics, combines therapy (thera) and diagnostics (ostics) to identify and target cancer cells for more effective treatment, while limiting damage to surrounding healthy tissue."

The initial PRIMARY trial evaluated the combination of this imaging technique with magnetic resonance imaging (MRI) to improve prostate cancer diagnosis by differentiating aggressive cancers from less significant disease. The trial results, published in European Urology, found significant improvement in the sensitivity and negative predictive value of the combined imaging approach, so that treatment could be targeted accordingly.

PRIMARY 2 is now underway at sites across Australia to evaluate whether the combined imaging technique can refine the diagnostic process so that patients may be subject to less intense surveillance in terms of the number and extent of prostate biopsies.

A further outcome of this work has been the development of the PRIMARY Score from PET imaging, a pattern-based score designed to differentiate low-risk and high-risk patients. The score is now included in the European Urology Guidelines for Prostate Cancer, again reflecting the power of clinical research to advance clinical practice.

"For us, the PRIMARY series of trials is like climbing a ladder, taking it step by step towards improving management and outcomes for more than 200,000 men currently living with prostate cancer and the 20,000 or more diagnosed each year" reflects Professor Emmett.

Phase 1 trial of implantable epilepsy-monitoring device

Helping people get their lives back

PROFESSOR MARK COOK AO

Chair of Medicine and Director of Clinical Neurosciences, St Vincent's Hospital Melbourne and Chief Medical Officer of Epiminder and Seer Medical

After decades of research and development, ambitions to enable long-term 24/7 monitoring of brain activity for people with refractory epilepsy are a step closer to fruition, with a Phase 1 clinical trial of an implantable device soon to be completed in Melbourne.

For Professor Mark Cook AO, Chair of Medicine and Director of Clinical Neurosciences at St Vincent's Hospital Melbourne and inventor of the device, the trial marks a significant milestone in his career-long commitment to improving the treatment of epilepsy and securing greater independence for those who live with this often-unpredictable condition.

"The key to improving treatment and helping people 'get their lives back' is being able to accurately monitor when seizures are occurring and under what circumstances," says Professor Cook. "Many seizures go undetected, simply because of the way they affect the brain, so relying on patient diaries has been a major barrier to understanding an individual's seizure pattern and optimising treatment. In turn this is a barrier to confidently predicting a person's safety for daily activities such as work and driving."

Professor Mark Cook AO

"St Vincent's has shared that vision and belief right from the conceptual beginnings, providing facilities to enable engagement between medical specialists, engineers, and data experts, as well as an organisation-wide commitment to research that links this expertise with patients and other clinicians."

Think Cochlear implant, and you will get a sense of the potential significance of this device. In fact, it was the Cochlear technology that set Professor Cook down this path of invention, ultimately partnering with Cochlear and the Bionics Institute in the development process.

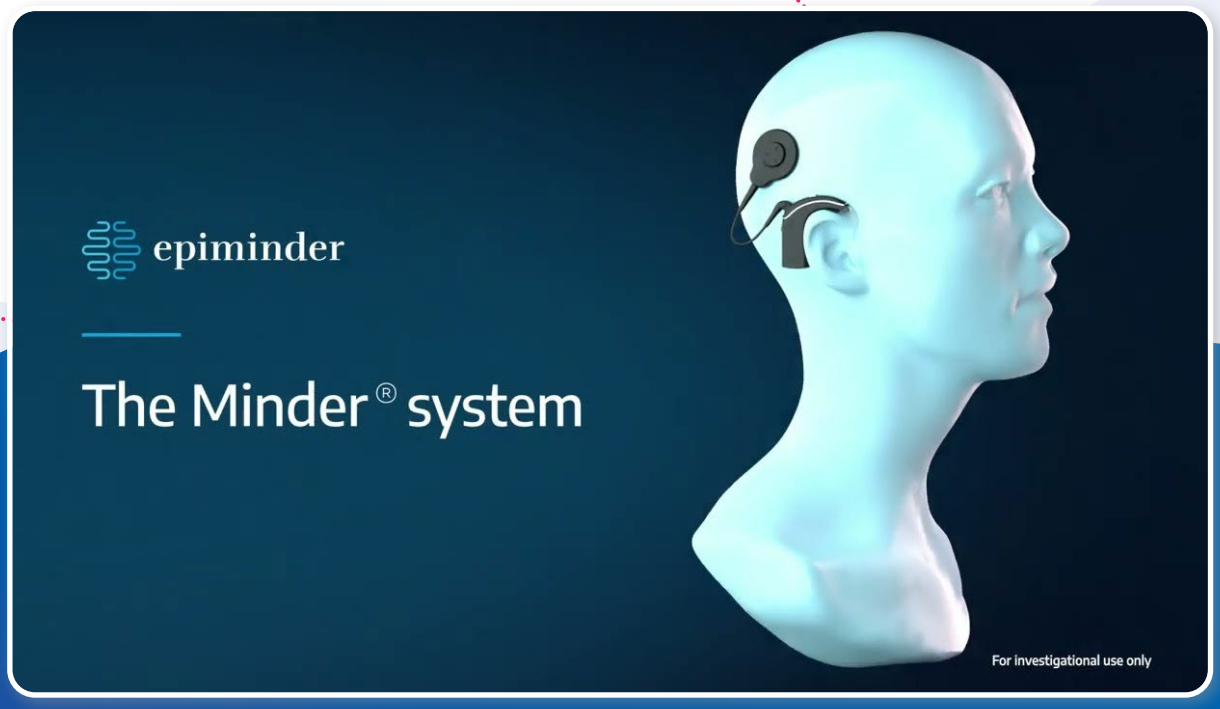
The minimally intrusive device (aptly called Minder®) captures brain activity through an implant secured under the scalp. A processor provides power to the implant and a Bluetooth connection to the smartphone, which in turn enables uploading of data to the cloud for processing. The Phase 1 trial is testing device data capability and safety.

As for many of our research breakthrough stories, Professor Cook's persistence and dedication have driven not only the clinical and technological aspects of the work, but also the crucial commercial and systems partnerships necessary to bring this complex and evolving vision to reality.

Professor Cook is quick to highlight the highly collaborative nature of such a complex project and the value of the support provided by St Vincent's over the project's long development.

"St Vincent's has shared that vision and belief right from the conceptual beginnings, providing facilities to enable engagement between medical specialists, engineers, and data experts, as well as an organisation-wide commitment to research that links this expertise with patients and other clinicians. This approach is the basis of the Aikenhead Centre for Medical Discovery (ACMD), co-located at our St Vincent's Fitzroy campus – getting different perspectives for better solutions to complex problems."

About a third of people with epilepsy are not well controlled with medication and stand to benefit most from long-term monitoring that will enable detection of seizures and monitoring of the impacts of treatment. Professor Cook's broader vision is for all people with epilepsy to be able to self-monitor and ultimately predict their seizures through blue tooth enabled technology - a much brighter future indeed.



The Minder® System

MonarchE trial

Reducing breast cancer recurrence in high-risk patients

PROFESSOR FRANCES BOYLE

Director of the Patricia Ritchie Centre for Cancer Care and Research, Mater Hospital, Sydney

Professor Frances Boyle

Great progress has been made in the treatment of early breast cancer over the past 20 years, with 5-year survival rawtes now exceeding 90 per cent. This has been achieved through improved screening and early detection, together with more accurate surgery and pathology, and more effective drug treatment to prevent recurrence (so called 'adjuvant therapy').

"Clinical trials are instrumental in driving these improvements", says Professor Fran Boyle, who leads the research team at the Mater and contributes to clinical trial development nationally and internationally through Breast Cancer Trials and the International Breast Cancer Study Group. "Here at the Mater, our Breast Cancer Clinical Trials Team plays an important role in advancing clinical care, partnering with clinicians and support teams at the Patricia Ritchie Centre."

Despite the improved outcomes overall, the risk of recurrence for some women with hormonal breast cancer remains high. Commonly these are women experiencing faster growing disease or potentially later diagnosis, with more tumour present in the breast and lymph nodes.

"Clearly better approaches are needed and our recent research efforts have focused on optimising adjuvant therapy to prevent early recurrence and metastases for these women. This includes our involvement in the international MonarchE trial"

"Clearly better approaches are needed and our recent research efforts have focused on optimising adjuvant therapy to prevent early recurrence and metastases for these women. This includes our involvement in the international MonarchE trial," says Professor Boyle, who represented Australia on the trial's international steering committee.

The randomised phase III trial investigates a relatively new class of drugs, CDK inhibitors, which enhance the effectiveness of hormone blocking treatment and have been used successfully over the last 5 years to improve survival in women with Stage 4 (metastatic) breast cancer.

This success spurred interest in using these medications earlier in treatment, with the MonarchE trial investigating whether 2 years of oral treatment with the CDK inhibitor abemaciclib and adjuvant hormone therapy could reduce early recurrences. The results published in 2020 gave an excellent signal of early effectiveness, with a significant improvement in invasive disease-free survival.

"The Mater had the highest recruitment of any Australian site," reflects Professor Boyle, whose team has also contributed to a "Real World" registry of these drugs, helping to build evidence of their value.

Beyond the direct involvement in this clinical trial, Professor Boyle and the Medical Oncology Group of Australia, have worked closely with consumer organisations such as Breast Cancer Network Australia, to help move this breakthrough in treatment through the pipeline to patients who need it. "We see this as an integral part of our research effort, to ensure Australian patients benefit from the involvement of their "sisters" in our trials."

Early phase cancer clinical trials at the Kinghorn Cancer Centre

Professor Anthony Joshua

PROFESSOR ANTHONY JOSHUA, DR RASHA COSMAN & DR JIA LIU

Early Phase Clinical Trial Unit, The Kinghorn Cancer Centre, St Vincent's Hospital Sydney

Access to clinical trials brings hope for many people with cancer and enables the cycle of discovery and translation that drives improvements in patient outcomes and quality of life.

These are strong motivators for researchers and clinicians at the Kinghorn Cancer Centre at St Vincent's Hospital in Sydney, where laboratory research findings move quickly into clinical care, helping to realise the promise of innovative personalised care for people with cancer.

"St Vincent's has always had a strong involvement in oncology research," notes Professor Joshua, who joined the Kinghorn Cancer Centre and the Garvan Institute of Medical Research in 2015, "But with the support of the hospital and through our partnership with the Garvan, we have expanded significantly, both in terms of the number and complexity of trials and the number of patients recruited. Indeed, the growth of our Early Phase Clinical Trials Unit has seen us become one of the top recruiting hospitals in Australia for early phase cancer trials."

"The passion for their work is evident as the team talks about the variety of trials in which they are involved, including investigator-initiated trials, cooperative group studies and pharmaceutical studies"

"We have 29 early phase trials open at the moment and actively recruiting, as well as a healthy pipeline of studies to activate before the end of year", says Dr Rasha Cosman, who is the medical lead of the unit, supported by specialist Dr Jia Liu and a team of ten trial coordinators, data managers and support staff. Awarded Outstanding Cancer Trials Unit in 2018, the unit owes its success to systematic and innovative approaches that address barriers to recruitment, rigorously assess scientific merit of potential trials, and optimise opportunities for collaboration and funding, all the while keeping a laser-sharp focus on the benefits for patients. "Everyone's focussed on what we're trying to do, which is to help patients", says Professor Joshua.

The passion for their work is evident as the team talks about the variety of trials in which they are involved, including investigator-initiated trials, cooperative group studies and pharmaceutical studies. "We are obviously excited about bringing our own discoveries and ideas to clinical trial, including novel uses for established treatments.

In a current example we are investigating early application of a drug traditionally used in metastatic melanoma, the aim being to shrink melanoma in the eyes, avoid surgical removal and save sight. As you can imagine, going home with your eyes intact is an amazing outcome for patients," says Professor Joshua.

Of course, for clinicians involved in clinical trials, the benefits are enormous in terms of fostering a culture of discovery and translation. "Our partnership with the Garvan enables us to cross appoint staff as both clinicians and researchers, which builds the research culture and more satisfying careers."

Outside the hospital, the group actively contributes to and influences the broader cancer clinical trial landscape through their involvement in Clinical Trials Australia, the New South Wales Early Phase Clinical Trials Alliance and WIN, Worldwide Innovative Networking in personalised cancer medicine.

The Early Phase Clinical Trial Unit at the Kinghorn Cancer Centre

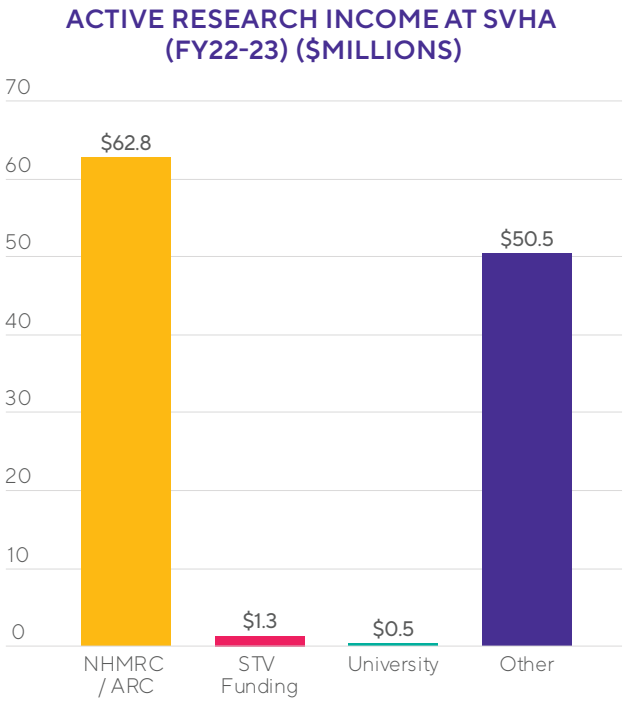
KPIs

KPIs are for the Financial Year of 2022 - 2023, unless otherwise stated.

$115,068,035

research income actively received by SVHA

NHMRC / ARC Grants	**$62,763,665**
St Vincent's Funding	**$1,328,020**
University	**$464,262**
Other	**$50,512,088**



1755
RESEARCH PUBLICATIONS
including journal articles and book chapters

327
HIGHER DEGREE RESEARCH (HDR) STUDENTS AT SVHA
including PhD Students and Other HDR Students (i.e. Masters and Honours)

89
AWARDS RECEIVED BY SVHA RESEARCHERS

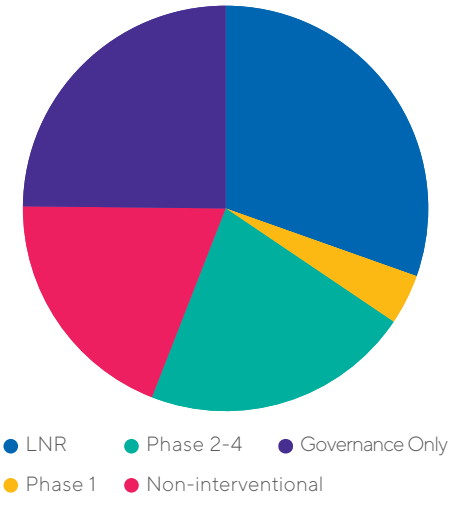
2928
OPEN AND ACTIVE CLINICAL STUDIES AT SVHA

1017
ACTIVE INTERVENTIONAL CLINICAL TRIALS AT SVHA

447
New Study Submissions to St Vincent's NMA-credentialed HRECs

Study Type	Number of New Studies Submitted
LNR	136
HREC Phase 1	18
HREC Phase 2-4	96
Non-interventional	86
Governance Only	111

NEW STUDY SUBMISSIONS (FY22-23)



Notes

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Talk to our team to learn more about the research valet® service

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ACKNOWLEDGMENT OF COUNTRY

St Vincent's Health Australia acknowledges Aboriginal and Torres Strait Islander peoples as the Traditional Custodians of the lands and waters where we live and work. We respect their historical and continuing spiritual connections to country and community and pay our respects to their Elders past, present and emerging. As a health and aged care ministry, we commit ourselves to the ongoing journey of Reconciliation.

ST VINCENT'S HEALTH AUSTRALIA
UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES