

# Annual Research Report 2022 - 2024

Advancing patient care through  
innovative research and  
compassionate practice



**ST JOHN OF GOD**  
Subiaco Hospital

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# CEO Welcome

I am delighted to share the latest edition of St John of God Subiaco Hospital's Research Report, highlighting the incredible breadth of life-changing medical research conducted at our hospital across FY23 and FY24.

Over the years, St John of God Subiaco Hospital has become renowned for being at the forefront of clinical innovation and excellence. This reputation is underpinned by our continued investment in research across a wide range of specialties, conducted by our highly experienced research and clinical trials teams comprised of medical specialists, nurses and midwives, research coordinators and allied health professionals.

In the past two years alone, our research team members conducted 62 research projects and 72 clinical trials related to gynaecology, inflammatory bowel disease, intensive care, oncology, orthopaedics, respiratory medicine and palliative care, as well as nursing services.

Of these projects, 54 were specific to oncology, cementing St John of God Subiaco Hospital's position as one of the most active private cancer research institutes world-wide, and a provider of the latest cancer care and treatments available.

We are incredibly proud that research conducted at our hospital is resulting in Western Australia having some of the highest survival rates in the world for certain cancer types including pancreatic, ovarian, colon and stomach cancers.

Our reputation as a leading research institute was reinforced in November 2023, when the hospital was recognised by the Australasian Gastro-Intestinal Trials Group (AGITG) as Australia's most outstanding clinical trial site.

St John of God Subiaco Hospital received the 2023 AGITG Outstanding Metropolitan Site Award, which celebrates a site that has shown exceptional enthusiasm, performance and dedication to conducting trials related to gastro-intestinal (GI) cancers - including those of the oesophagus, stomach, liver, pancreas, gallbladder, large and small bowel, rectum and anus.

This award is testament to the incredible efforts of all members of the Clinical Trials Unit, including St John of God Subiaco Hospital oncologists Associate Professor Tim Clay, Dr Andrew Dean and Dr Tom van Hagen, as well as caregivers from our Bendat Family Comprehensive Cancer Centre.

As we progress the major redevelopment of our campus, research remains central to our Vision of building on our hospital's legacy of providing person centred medical care in a contemporary environment which supports hospitality, healing and hope.

Our Subiaco Hospital site master plan includes an 11 storey medical suites, education and research building, where pioneering treatments and care will be developed. And most importantly, where patients and their loved ones will be provided hope and healing with compassion.

I would like to take this opportunity to thank all members of our incredible research and clinical trials teams. Your commitment to your patients, to the advancement of health care and to the understanding and treatment of illness is truly inspiring. Our hospital is incredibly fortunate to benefit from your expertise and service.

I also express my thanks to all of our valued donors. Your partnership and financial support is essential to the continuation of research excellence at our hospital and enabling ongoing advancements in medical care.

**Tina Chinery**  
**Chief Executive Officer**



Subiaco Hospital proposed redevelopment (artist impression)



# Director of Research

The healthcare landscape is evolving rapidly, driven by technological advancements, changing patient expectations, and a growing emphasis on value-based care. As medical professionals, we have a profound responsibility to not only keep pace with these changes but to lead the way in improving patient outcomes and experiences.

At the heart of our mission lies the unwavering commitment to enhancing patient care. This requires a multifaceted approach that encompasses clinical excellence, compassionate service and placing the patient at the forefront of all that we do. By continually refining our practices and embracing evidence-based innovations, we can elevate the standard of care we provide.

Research governance is the cornerstone of ethical, high-quality, and impactful scientific inquiry. At our institution, we have made significant strides in developing a robust research governance framework to support and guide our investigators in their pursuit of knowledge and innovation.

Central to our efforts is the establishment of the Research Governance Committee (RGC). This committee plays a pivotal role in overseeing and enhancing our research practices, ensuring compliance with ethical standards, and promoting best practices across all disciplines. The RGC has developed valuable resources for our researchers, including comprehensive guidelines for good research practice and tailored training programs.

Our Research management team provides practical assistance in helping our research teams write and understand clinical trial protocol, as well as assisting with trial design, framing research questions and enhancing the methodology of our studies. Statistical support is also enabled.

SJG Subiaco Hospital has fostered the growth of several dynamic research groups: respiratory and cardiothoracic surgery, clinical oncology, breast cancer, gynaecologic oncology, colorectal surgery, intensive care medicine, orthopaedic surgery, anaesthesia and pain medicine, and allied health, nursing and midwifery. In addition, we recognise and celebrate the invaluable contributions of individual researchers working outside these structures. Our aim is to create an ecosystem where both collaborative teams and independent investigators can thrive, leveraging their unique strengths to advance our collective scientific endeavours.

Our Clinical Trials Unit stands as a testament to our commitment to translational research. This unit serves as a crucial bridge between laboratory discoveries and patient care, facilitating the rigorous evaluation of new therapies and interventions. Its importance in our research landscape cannot be overstated, as it enables us to bring promising innovations to the bedside efficiently and safely.

It gives me great pleasure to welcome both Dr Angela Baird and Dr Natalya Beer to the substantive roles of Manager of the Research Department and Manager of the Clinical Trial Unit within our research community. Their expertise and vision will undoubtedly strengthen our research governance and drive us towards new horizons of scientific excellence.

As we look to the future, we face both challenges and exciting opportunities. The rapidly evolving landscape of research ethics, particularly in areas such as data privacy and emerging technologies, demands our constant vigilance and adaptation. However, these challenges also present opportunities for innovation in our governance practices and for establishing ourselves as leaders in responsible research conduct. The increasing emphasis on interdisciplinary collaboration opens new avenues for groundbreaking discoveries. By fostering connections across traditional boundaries, we can tackle complex problems with fresh perspectives and combined expertise.

Our commitment to robust research governance, coupled with the diverse talents of our researchers and the strategic infrastructure we have put in place, positions us well to continue to drive significant contributions to the scientific community and society at large. I look forward to the remarkable achievements that lie ahead as we navigate this exciting journey together and trust that you will enjoy reading about our researchers and their achievements in the following pages.

**Professor Eli Gabbay**  
**Director of Research - Subiaco Hospital**



**62**  
Active Research  
Studies

St John of God Subiaco  
Hospital was awarded the  
2023 Outstanding  
Metropolitan Site Award  
by the Australasian  
Gastro-Intestinal Trials  
Group (AGITG)

**112**  
Publications

**905**  
Patients  
Recruited in the  
last 2 years

**74**  
Active Clinical  
Trials

**Snapshot**  
**2022 -2024**

# Manager Research and Manager Clinical Trials Foreword

We are proud to present the research highlights from the past two years. The rapid evolution of medical research presents both challenges and exciting opportunities, and our teams are dedicated to staying at the forefront of innovation to improve patient care. Our research efforts are closely aligned with our core clinical services—orthopaedics, respiratory and cardiothoracic medicine, breast and colorectal surgery, intensive care, anaesthesia and pain medicine, nursing and midwifery and oncology—ensuring our work directly benefits the hospital and our broader community.

This period has seen significant milestones, including recognition by the Australasian Gastro-Intestinal Trials Group (AGITG), which awarded us the Outstanding Metropolitan Site Award. Our clinical trial unit has been pivotal in advancing oncology treatments, with several trials contributing to the approval of new anti-cancer therapies now available on the Australian Pharmaceutical Benefits Scheme. These practice-changing trials provide patients with life-prolonging treatments, reinforcing our hospital's role in transforming cancer care.

A key driver of our success is the talented and dedicated team of clinicians, researchers, and support staff. Their enthusiasm and passion for advancing healthcare have propelled us forward, and we continue to invest in training and development to ensure our team stays equipped to handle trials of increasing complexity. This multidisciplinary approach fosters innovation and collaboration, with several breakthrough studies, particularly in minimally invasive surgical techniques and personalized treatment protocols, making a tangible impact on patient outcomes.

We would like to extend our heartfelt thanks to the St John of God Foundation for supporting research project development and early career researchers, which is crucial to sustaining a vibrant and inclusive research culture at Subiaco Hospital. We also recognize the importance of engaging with our patients and the community. Our research priorities reflect real-world needs, and we are focused on ensuring that the research we conduct translates into improvements in care.

As we look to the future, we are excited by the potential to continue making meaningful contributions to healthcare. The support from our community partners and donors has been instrumental in driving these advancements, and we look forward to our continued work in creating a legacy of excellence in healthcare research.



**Dr Angela Baird**  
Manager Research



**Dr Natalya Beer**  
Manager Clinical Trials



# Anaesthesia and Pain Research Unit

The Anaesthesia and Pain Research Unit remains committed to improve outcomes for patients undergoing surgery. Key research priorities remain focused at reducing post-operative acute and chronic pain, wound infection and cancer reoccurrence.

Prevention of Chronic Post-Surgical Pain (CPSP) is seen as the “Holy Grail” of anaesthesiology; it remains a common and debilitating complication of surgery. The ROCKeT and LOLIPOP trials are investigating treatments into CPSP that could provide the evidence to transform routine anaesthesia practice worldwide and improve patients’ quality of life and the associated financial healthcare burden.

Surgical site infection (SSI) remains a serious and expensive postoperative complication. The TRIGS trial examines an innovative way to reduce SSI in gastrointestinal surgery, and will evaluate the effects on immune and inflammatory responses. The CALIPSO trial is aimed at SSI in patients undergoing cardiac surgery.

The TRIGS and ROCKeT sub-studies are evaluating the incidence and severity of delirium after surgery. Delirium is a devastating complication of medical and perioperative care, associated with increased morbidity and mortality, dementia and impaired long-term cognition, and loss of independence. Delirium is also associated with neuronal injury placing patients at risk for long-term changes in cognition. There are no proven therapies for postoperative delirium, mainly due to the lack of adequately powered, biologically plausible trials.

Team : Prof Tomas Corcoran (PI), Dr James Preuss, Ms Yvonne Buller, Ms Louise Bowles, Ms Natalie Hird



*Dr James Preuss was a finalist in the Gilbert Brown Prize Session, ANZCA Annual Scientific Meeting for the presentation “The diagnostic accuracy of ROTEMsigma® FIBTEM amplitude measurements for the identification of hypofibrinogenaemia in cardiac patients is improved by considering the ratio of the FITEM to the EXTEM clotting time” 2022.*

## Publications

Toner AJ, Corcoran TB, Vlaskovsky PS, Nierich AP, Bain CR, Dieleman JM: Inflammation risk before cardiac surgery and the treatment effect of intraoperative dexamethasone. *Anaesth Intensive Care* 2024, 52(1):28-36. <https://doi.org/10.1177/0310057X231195098>

Myles PS, Corcoran TB, Chan MT, Asghari-Jafarabadi M, Wu WKK, Peyton P, Leslie K, Forbes A: Intraoperative dexamethasone and chronic postsurgical pain: a propensity score-matched analysis of a large trial. *Br J Anaesth* 2024. <https://doi.org/10.1016/j.bja.2023.12.031>

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# Breast Cancer Research Unit

Breast Cancer is the most commonly diagnosed cancer amongst women in Australia. With approximately 57 Australians diagnosed each day (NBCF) The Breast Cancer Research Unit addresses three major aspects to assist and guide patient care -

- To address issues experienced by breast cancer survivors following completion of the active treatment i.e. surgery, chemotherapy, radiotherapy, targeted therapy, aiming to improve quality of life outcomes.
- To monitor and report rate of ipsilateral breast tumour recurrence and rate of regional recurrence, disease free survival and overall survival of patients who are treated with Intra-Operative Radiotherapy Treatment (IORT).
- To monitor and report on Patient Reported Outcome Measures (PROMs) in patients who are treated with IORT during breast conserving surgery.

## *Intra – Operative Radiotherapy (IORT) for Early Breast Cancer Outcomes Data Register*

*SJGSH is the only private hospital in Australia offering Intraoperative Radiotherapy (IORT) for select women with early breast cancer. IORT reduces treatment time from three – seven weeks of daily radiation to a single targeted treatment administered while the patient is undergoing breast conserving surgery / lumpectomy to remove the cancer.*

*The purpose of the registry is to track short and long term outcomes of patients with early breast cancer who are treated with intra-operative radiotherapy. To date 172 patients have received IORT. Information on patient's breast cancer diagnosis and general health are collected. Findings from this registry may be used to support changes to standard practice in the future, and will be a valuable resource in assessing the safety and quality of IORT. It is hoped that IORT becomes more common in treating early breast cancer because of the potential benefits to patients – both in treating cancer as well as reducing the number of appointments and radiotherapy sessions patients have to attend.*

Team : Dr Helen Ballal, Dr Lee Jackson, Dr Wen Chan Yeow, Dr Corrine Jones, Dr Ming Yew, Ms Gay Refeld

## Publications

Gay Refeld, Christobel Saunders, Alannah Cooper, Niloufer Johansen, Elizabeth Sorial. A Multi Method Evaluation of a Specialist Breast Care Nurse Led Survivorship Clinic.  
<https://doi.org/10.1188/23.onf.753-764>



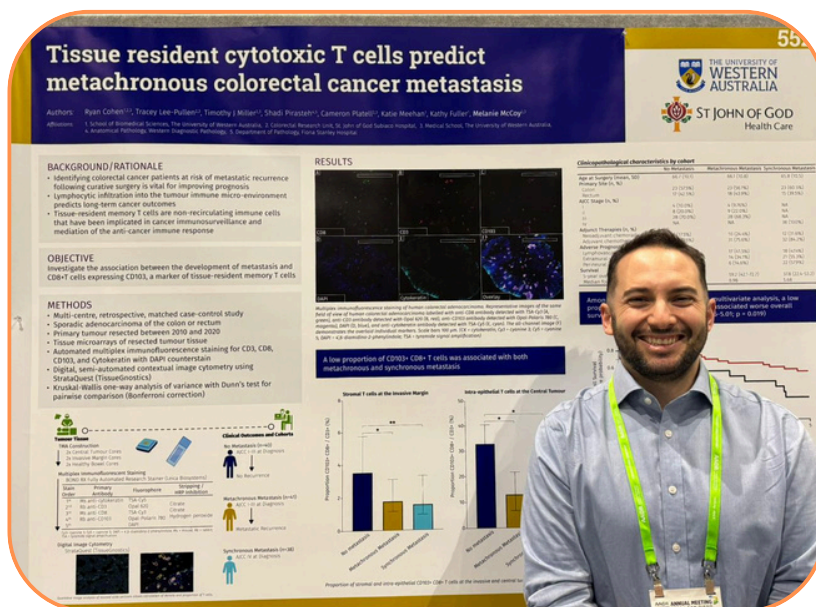
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# Colorectal Cancer Research Group

More than 1500 people are diagnosed with colorectal (bowel) cancer in Australia every year. Despite continual improvements in diagnosis and treatment, almost one in three people still sadly die from the disease\*. Of those who survive, many experience long-term side-effects from the treatment they receive. Within the colorectal cancer research group, clinicians, scientists and laboratory staff work closely together towards

- Improving survival and quality of life for patients with colorectal cancer
- Biomarkers of prognosis and treatment response
- Harnessing the immune system to fight colorectal cancer
- Finding ways to better predict the risk of disease recurrence and metastases

\*Data from the Australian Institute of Health and Welfare.



Dr Melanie McCoy presented at the Australasian Gastro-Intestinal Trials Group Annual Scientific Meeting 2022 in Melbourne, VIC, winning the Best of Posters Award for the group's work investigating the role of the immune system in influencing response to chemoradiotherapy.

Dr Ryan Cohen, presenting at the American Association for Cancer Research (AACR) Annual Scientific Meeting, held in San Diego, USA

Team : Dr Mel McCoy, Dr Jen Ryan, Ms Tracey Lee-Pullen , Dr Ryan Cohen, Ms Naressa Yeo

## Publications

Cohen R, Lee-Pullen T, Miller TJ, Meehan K, Fuller K, McCoy MJ. Optimising multiplex immunofluorescence staining for characterising the tumour immune micro-environment. *Methods* 2023, 219, 48-57.

<https://doi.org/10.1016/j.ymeth.2023.09.004>

Cohen R, Beasley A, McCoy M, Platell C, Meehan K, Gray E, Fuller K. Locally performed postoperative circulating tumour DNA testing performed during routine clinical care to predict recurrence of colorectal cancer. *ANZ J Surg* 2023, 93 2473-2480.

<https://doi.org/10.1111/ans.18385>

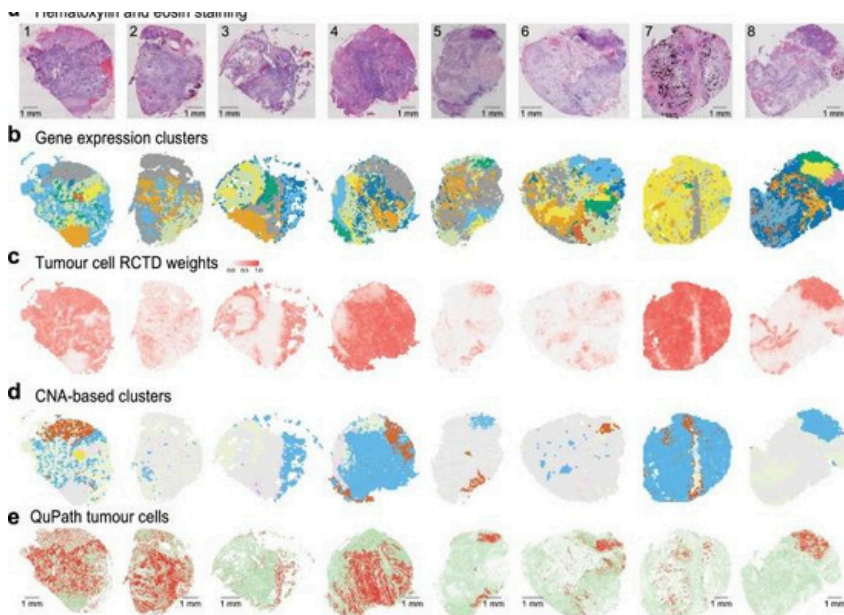
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# Gynaecological Cancer Research Group

According to the 2023 data in Australia more than 5900 women a year are diagnosed with a gynaecological malignancy including ovarian, endometrial, cervical and vulval cancers.

Our research aims to improve outcomes and quality of life for patients and focuses on patient-reported outcomes and the supportive care of those affected by gynaecological cancers. We also conduct research in gynaecological cancer genetics, the epidemiology of gynaecological malignancies, and biomarkers to predict relapse in women with high-grade serous ovarian cancer, the most common type of ovarian cancer. We are a recruiting site for clinical trials in gynaecological cancer and lead national and international multicentre randomised trials.



## *Perth researchers find some ovarian cancer cells appear to tell immune system to stay away.*

*Spatial transcriptomics reveals discrete tumour microenvironments and autocrine loops within ovarian cancer subclones” published in the journal Nature Communications.*

*A cross-town collaboration involving researchers from the Harry Perkins Institute of Medical Research, St John of God Subiaco Hospital, Curtin University, Clinipath, The University of Western Australia (UWA) and Edith Cowan University has found that ovarian tumours alter their local environment by*

*changing the sets of messages they send to cells nearby.*

*Using an advanced technique known as spatial transcriptomics the team generated cellular maps of ovarian cancer samples from patients in Perth who donated their tumours for research.*

*(Harry Perkins Institute of Medical Research)*

Team : Prof Paul Cohen, Ms Sanela Bilic, Ms Maria Beilin, Ms Issy Black

## Publications

Denisenko, E., de Kock, L., Tan, A., Beasley, A. B., Beilin, M., Jones, M. E., Hou, R., Muirí, D. Ó., Bilic, S., Mohan, G. R. K. A., Salfinger, S., Fox, S., Hmon, K. P. W., Yeow, Y., Kim, Y., John, R., Gilderman, T. S., Killingbeck, E., Gray, E. S., ... Forrest, A. R. R. Spatial transcriptomics reveals discrete tumour microenvironments and autocrine loops within ovarian cancer subclones. *Nature Communications* 2024, 15(1), Article 2860. Advance online publication. <https://doi.org/10.1038/s41467-024-47271-y>

Cohen, P. A single arm pilot observational study to evaluate the safety and feasibility of a pre-operative very low calorie diet in severely obese patients with endometrial cancer. *International Journal of Gynecological Cancer* 2024, 34(A150-A151). Advance online publication.

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# Intensive Care Research Group

The ICU Research Group are involved in a range of quality improvement and research projects. We support medical students and junior doctors to conduct audits, lead observational and interventional studies initiated at Subiaco Hospital, and contribute to large, national and international investigator-initiated studies.

Key Research Areas are improving outcomes for patients undergoing cardiothoracic surgery, reducing the incidence and severity of delirium, treating anaemia in the critically ill, measuring and reporting on patient experiences and outcomes (PROEMS/PROMS), embedding research in Clinical Quality Registries, and the treatment of Community Acquired Pneumonia and COVID 19-related pneumonia.

The COVID 19 pandemic remained a major focus of the ICU research group during 2022/2023. Group members have led research on the national ICU resources available to meet the needs of critically ill patients in a pandemic, as well as the characteristics and outcomes of Australians with severe COVID over the course of the pandemic, as new treatments have been introduced and new challenges have emerged.

Team : A/Professor Kwok Ho, John Lewis, Head of ICU Department, Prof Ed Litton, Prof Steve Webb - Director of Research SJGHC, Ms Janet Ferrier, Ms Lesley Kemp

## PUBLICATIONS

Ed Litton, Thirty years of ANZICS CORE: A clinical quality success story.  
<https://doi.org/10.1016/j.ccrj.2023.04.009>

Ed Litton, Weaning from mechanical ventilation in intensive care units across 50 countries (WEAN SAFE): a multicentre, prospective, observational cohort study.  
[https://doi.org/10.1016/s2213-2600\(22\)00449-0](https://doi.org/10.1016/s2213-2600(22)00449-0)

Steve Webb, Collaborator Ed Litton, Dexmedetomidine and Propofol Sedation in Critically Ill Patients and Dose-associated 90-Day Mortality: A Secondary Cohort Analysis of a Randomized Controlled Trial (SPICE III).  
<https://doi.org/10.1164/rccm.202206-1208oc>

## ICU PROJECTS

**ANZICS PROEMS** - Patient Reported Outcome and Experience Measures (PROEMS) Pilot Feasibility Study.

200,000 Australians require admission to an intensive care unit (ICU) each year. ANZICS PROEMS is a world first study for which SJOG Subiaco ICU is a vanguard site. Collecting patients and their family members perception of health function and care experience from ICU will help ICU clinicians to improve care and have a greater understanding of the challenges facing patients after a stay in ICU. SJOG Subiaco is leading the way in ICU follow up with the highest response rate nationally.

**iTHRIVE Trial** - Iron and Erythropoietin to heal and recover after intensive care; a multi-centre, randomised, placebo-controlled clinical trial of intravenous iron and erythropoietin in critically ill adults.

The iTHRIVE clinical trial is designed to evaluate whether treating anaemia can improve outcomes for ICU patients. The study is recruiting nationally and recently opened at SJGSH with the first patient recruited in May 2024.

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# Orthopaedic Research

Perth Hip and Knee Clinic is actively involved in orthopaedic research focused on hip and knee joint replacement surgery. The clinic consists of four experienced hip and knee joint replacement surgeons who perform approximately 1,200 joint replacement surgeries per year. Since opening in November 2015, Perth Hip and Knee has been building a research database that now includes over 2,500 enrolled patients. This database has reached a level of maturity that allows for analysis and meets requirements for international publications.

They have a robotic total knee database with over 1,900 patients enrolled, capturing preoperative, intraoperative, and postoperative data as well as clinical outcomes. This is considered one of the most comprehensive databases on this emerging technology worldwide.

Perth Hip and Knee surgeons are approved to use new limited release Mako THR software for robotic planning and analysis in total hip arthroplasty. Current research interests focus on optimising and individualising total knee replacement planning, with a leading role in developing and assessing functional alignment techniques in total knee arthroplasty.

The clinic collaborates with national and international surgical research groups to facilitate orthopaedic research. Their ultimate aim is to improve outcomes for patients undergoing total knee arthroplasty through their research efforts.

This research activity demonstrates Perth Hip and Knee's commitment to advancing orthopaedic surgical techniques and improving patient outcomes in hip and knee joint replacement procedures.



## PUBLICATIONS

Armendariz, M., Tadros, B.J., Collopy, D., Clark, G. No evidence of mid-flexion instability after robotic-assisted total knee arthroplasty as assessed by intraoperative pressure sensors. Arthroplasty 6, Article number: 32 (2024)

<https://doi.org/10.1186/s42836-024-00253-3>

Nixon, J., Tadros, B.J., Moreno-Suarez, I., Pretty, W., Collopy, D., Clark, G. Functionally aligned total knee arthroplasty: A lateral flexion laxity up to 6mm is safe! KSSTA Knee Surgery Sports Traumatology Arthroscopy Vol 32, Issue 5, May 2024, pages 1317-1323

<https://doi.org/10.1002/ksa.12087>

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# WA Thoracic Research Group

The WA Thoracic Research Group is the largest respiratory and respiratory oncology research group in Western Australia's private health sector.

This group plays an important role in advancing research and clinical excellence in respiratory medicine and cancer-related pathologies. Their work contributes to improving patient care and outcomes across a range of respiratory and thoracic conditions.

With the generous donations from the Bendat Family it has enabled the group to continue to undertake research with an aim to improve clinical practice and provide high quality care to patients.

## PUBLICATIONS

Wilson, C. L., McLaughlin, C., Cairncross, A., Gabbay, E., Noble, P. B., Blakey, J. D., & Crawford, A. L. (2024). Home spirometry appears accurate and feasible for monitoring chronic respiratory disease. *ERJ Open Research*, 10(3) <https://10.1183/23120541.00937-2023>

Gabbay, E. Chest X ray is inferior to reduced dose CT for silicosis screening in a crossover study of Western Australian Stonemasons. *JOEM* (In press 2024)



Team : Dr Clement Lim, Tara Hannon, Dr KP Lim, Prof Eli Gabbay, Donna Cribb, A/Prof Tim Clay, Dr Andrew Byrne, Nisha Sikotra (absent)

## Research highlights

- Published their first study to be funded by the National Health and Medical Research Council (NHMRC) on Pulmonary Arterial Hypertension (PAH) in Scleroderma.
- Collaborative work focused on the early identification, assessment, and treatment of silicosis in stonemasons, which aims to improve diagnostic methods and treatment options for workers exposed to respirable crystalline silica dust, particularly those in the engineered stone industry.
- In collaboration with Sir Charles Gairdner Hospital (SCGH), they investigated the utility of home spirometric assessment in various lung diseases. This research aimed to empower patients in managing their own healthcare by providing them with tools for self-monitoring.
- Dr Andrew Byrne - Bendat Clinical Research Fellow Respiratory Medicine & Oncology - explored the use of critical incidents as a means to drive education and implement changes in medical practice, contributing to improved patient safety and healthcare quality.
- The team is involved as an inaugural centre and the only private hospital in the ANTHCOR registry of thoracic surgery.
- Ongoing involvement in the Interstitial Lung Disease (ILD) registry, with over 400 patients discussed at their Multidisciplinary ILD meetings in the last 12 months. This significant contribution is supported by the Bendat Family Respiratory Research and Development Fund.

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# Nursing & Midwifery Research

Our nursing and midwifery research program utilises an evidence-based approach to improving clinical care, service delivery, and health outcomes.

We encourage nurses and midwives to investigate and trial new processes that could benefit patient care, with projects spanning, maternity, palliative care, and general nursing care.

Nurses and midwives are uniquely placed to identify areas for research to improve patient care and experience, as the professions with the most frequent patient contact.

Our key research areas aims to -

- Improve outcomes for patients, their families and caregivers, by supporting nursing and midwifery research projects across St John of God Subiaco Hospital
- Support an active culture of nursing and midwifery research within the hospital
- Enable clinical nurses and midwives to initiate and conduct research projects across specialties such as maternity, general medicine and palliative care
- Share our research findings, which we do by presenting at external conferences and through journal publications.



Researcher : Dr Alannah Cooper

## PUBLICATIONS

Cooper, A. L., Albrecht, M. A., Kelly, S., Eccles, S. P., & Brown, J. A. (2024). A pre-post interventional study to reduce time spent on clinical documentation by nurses and midwives. *Journal of Advanced Nursing*. [doi.org/10.1111/jan.15931](https://doi.org/10.1111/jan.15931)

Cooper, A. L., Brennan, M., Leslie, G. D., & Brown, J. A. (2023). Integrating alternate data sources in mixed methods research. *Journal of Mixed Methods Research*. [doi.org/10.1177/15586898231188500](https://doi.org/10.1177/15586898231188500)

*This unit was awarded two grants from the St John of God Foundation in 2022 for the research projects 'Identifying barriers to palliative care access: A mixed methods study' and 'Developing an instrument to measure nurse resilience'*

*'Defining the influence of external factors on nurse resilience' was one of the top downloaded articles for 2022 for the International Journal of Mental Health Nursing*

*Dr Alannah Cooper was a finalist in the Excellence in Research category in the WA Nursing & Midwifery Excellence Awards in 2023 and 2024.*

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# Pharmacy

The last twelve months have seen the SJG Subiaco Hospital Pharmacy team continue to participate in, and support research and clinical trials cross our site.

Three abstracts were recently submitted by pharmacists to the Australian Medicines Management Conference 2024, highlighting the exciting clinical and service improvement projects currently underway across the site. The Antimicrobial Stewardship (AMS) Pharmacists have also recently received approval to use the PenFAST tool (created by Austin Health) to assess patients with a reported penicillin allergy to determine if they would be suitable for direct oral penicillin challenge and introduce this to the weekly AMS round.



The SJG Pharmacy Clinical Trial Team have made important contributions to SJOG Subiaco Hospital's Clinical Trial and Research team. Their growing expertise has led to the creation of a new Senior Clinical Trials Pharmacist role, recognising the unique experience and knowledge required to support this unit and highlighting the value of this service. This specialist pharmacy service is fully integrated with the hospital pharmacy and the SJG clinical trials team and provides contemporary and comprehensive medication management services for investigation medicines.

This team has driven the development of standard operating procedures for Investigational Drug Management in Research, tailored to streamline clinical trial hospital processes, improving consistency, compliance, and patient safety across departments. The Subiaco Hospital Pharmacy Clinical Trial Team have also taken the lead in procuring a specialised freezer, essential for storing particular investigational drugs and opening this site's opportunities for future clinical trials.

Additionally, there has been recent piloting of Clinical Trial Pharmacists gathering comprehensive medication histories from trial participants during screening procedures. This process ensures concomitant medications are reviewed prior to trial treatment commencement, ensuring protocol requirements are met and reducing the risk of potential adverse drug interactions.

In addition, 2024 has seen work initiated on the implementation of a new investigational drug software solution, nCoup, aimed at improving drug accountability, streamlining efficiencies, and optimising business processes.

So an exciting year for the SJG Pharmacy Team's contributions to Subiaco Hospital's Research and Clinical Trials service.

**Peter Smart - Chief Pharmacist**



# Clinical Trial Unit

The Subiaco Clinical Trial Unit has a strong record of providing vital treatment opportunities for patients consistent with the Hospital's clinical service provision. Areas of focus include pancreatic, ovarian, endometrial, breast, lung, upper gastrointestinal, prostate, renal and colorectal cancers. The Unit engages in commercially-sponsored, Investigator-initiated and Cooperative Research Group trials, from early-phase first-in-human, to late phase trials, with a specific focus on areas of unmet need. Currently, over 50 trials are active in the Unit, and strong interest continues to be received from commercial sponsors and external collaborators to participate in future trials. The treatment options available via clinical trials provide hope to patients and allow St John of God Subiaco Hospital to be at the forefront of new treatment discoveries.



*St John of God Subiaco Hospital was awarded the 2023 Outstanding Metropolitan Site Award by the Australasian Gastro-Intestinal Trials Group (AGITG) - Dr Andrew Dean and Dr Tara McSweeney accepting the Award.*

## KEY MILESTONES ACHIEVED

**ASCEND:** St John of God Subiaco Hospital was the highest recruiting site globally for the ASCEND clinical trial with 25 patients consented and 19 enrolled.

**CAMBRIA-1:** St John of God Subiaco Hospital was the first site activated in Australia and holds the position of highest recruiting site in Australia, to date.

**KEYNOTE-942:** St John of God Subiaco Hospital is the only Australian site to participate in the Phase 2 expansion of the mRNA-4157 trial.

**DESTINY 2 & DESTINY 3:** Results from these trials, which included patients from St John of God Subiaco Hospital, contributed to the overall analysis of over 12,000 patients from a total of four trials of trastuzumab deruxtecan (ENHERTU). ENHERTU has since been listed, in November 2023, on the Australian Pharmaceutical Benefits Scheme (PBS) for metastatic (Stage IV) HER2-positive breast cancer.

**KEYNOTE-775:** St John of God Subiaco Hospital contributed to this trial which provided key confirmatory data for the Pharmaceutical Benefits Advisory Committee (PBAC) to support listing of Pembrolizumab in combination with Lenvatinib for advanced, metastatic or recurrent endometrial cancer, on the PBS in June 2023.

**MONARCH E & MONARCH 2:** St John of God Subiaco Hospital contributed in both trials which provided data to the PBAC to support listing Abemaciclib as the first CDK4/6 inhibitor on the PBS for early breast cancer (HER2 negative, ER/PR positive, high risk of recurrence early breast cancer) in combination with endocrine therapy.

**Unit Contact: [ClinicalTrials.Subiaco@sjog.org.au](mailto:ClinicalTrials.Subiaco@sjog.org.au) - Phone (08) 6465 9204**

# Clinical Trials Activity

## Clinical trials open to recruitment: Current

**ZN-c3-005:** A Phase 2 Open-Label, Multicenter Study to Evaluate Efficacy and Safety of ZN-c3 in Subjects with High-Grade Serous Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Principal Investigator: Dr Tarek Meniawy

Opened to recruitment: June 2024

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**Beamion LUNG-2:** A Phase III, Open-Label, Randomised, Active- Controlled, Multi-Centre Trial Evaluating Orally Administered BI 1810631 Compared With Standard Of Care As First-Line

Treatment In Patients With Unresectable, Locally Advanced Or Metastatic Non- Squamous Non-Small Cell Lung Cancer Harboursing HER2 Tyrosine Kinase Domain Mutations

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: May 2024

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**GLORIOSA:** Randomised, Multicenter, Open-Label, Phase 3 Study Of Mirvetuximab Soravtansine In Combination With Bevacizumab Versus Bevacizumab Alone As Maintenance Therapy For Patients With Fr $\alpha$ -High Recurrent Platinum-Sensitive Epithelial Ovarian, Fallopian Tube, Or Primary Peritoneal Cancers Who Have Not Progressed After Second-Line Platinum-Based Chemotherapy Plus Bevacizumab (IMGN853-0421)

Principal Investigator: Dr Andrew Dean

Opened to recruitment: April 2024

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**OPTIMA:** Optimal Personalised Treatment of Early Breast Cancer Using Multi-Parameter Analysis

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: April 2024

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**KEYNOTE-942:** A Phase 2 Randomised Study of Adjuvant Immunotherapy With the Personalised Cancer Vaccine mRNA-4157 and Pembrolizumab Versus Pembrolizumab Alone After Complete Resection of High-Risk Melanoma (mRNA4157-P201)

Principal Investigator: Dr Tarek Meniawy

Opened to recruitment: September 2023

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**CAMBRIA-1:** A Phase III, Open-Label, Randomised Study to Assess the Efficacy and Safety of Extended Therapy with Camizestrant (AZD9833, a Next Generation, Oral Selective Estrogen Receptor Degradar) versus Standard Endocrine Therapy (Aromatase Inhibitor or Tamoxifen) in Patients with ER+/HER2- Early Breast Cancer and an Intermediate or High Risk of Recurrence Who Have Completed Definitive Locoregional Therapy and at Least 2 Years of Standard Adjuvant Endocrine-Based Therapy Without Disease Recurrence

Principal Investigator: Dr Daphne Tsoi

Opened to recruitment: August 2023

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**BCB-LC-201:** A Phase 2, Open-label, Multi-arm Study of Tislelizumab in Combination With Investigational Agents With or Without Chemotherapy in Patients With Previously Untreated, Locally Advanced, Unresectable, or Metastatic Non-Small Cell Lung Cancer

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: July 2023

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**iLSTA:** A Safety And Early Efficacy Study Of LSTA1 In Combination With Durvalumab, Gemcitabine And Nab-Paclitaxel, As First- Line Treatment In Locally Advanced Exocrine Pancreatic Cancer

Principal Investigator: Dr Andrew Dean

Opened to recruitment: March 2023

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KAT6i: A Phase 1 Dose Escalation And Expansion Study To Evaluate Safety, Tolerability, Pharmacokinetic, Pharmacodynamic, And Anti-Tumor Activity Of PF-07248144 In Participants With Advanced Or Metastatic Solid Tumors (Protocol No. C4551001)  
Principal Investigator: A/Prof Timothy Clay  
Opened to recruitment: April 2022

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MK-3475-587: A Multicenter, Open-label, Phase III Extension Trial to Study the Long-term Safety and Efficacy in Participants with Advanced Tumors Who Are Currently on Treatment or in Follow-up in a Pembrolizumab Trial  
Principal Investigator: Dr Andrew Dean  
Opened to recruitment: April 2021

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CAPTURE: Circulating tumour DNA Assessment of PIK3CA to Guide Treatment Response (BCT 1901)  
Principal Investigator: Dr Daphne Tsoi  
Opened to recruitment: October 2020

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BRCA-P: A Randomised, Double-Blind, Placebo-Controlled, Multi-Center, International Phase 3 Study to Determine the Preventive Effect of Denosumab on Breast Cancer in Women Carrying a BRCA1 Germline Mutation  
Principal Investigator: Dr Helen Ballal  
Opened to recruitment: August 2020

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### **Clinical trials opened to recruitment during FY23 and FY24 (currently active and closed to recruitment)**

ProviDHe: An Open-Label Early Access Phase 3b Study of Ivosidenib in Patients With a Pretreated Locally Advanced or Metastatic Cholangiocarcinoma (DIM-95031-002)  
Principal Investigator: Dr Andrew Dean  
Opened to recruitment: August 2023

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HER2CLIMB-05: A Randomised, Double-Blind, Phase 3 Study Of Tucatinib Or Placebo In Combination With Trastuzumab And Pertuzumab As Maintenance Therapy For Metastatic HER2+ Breast Cancer (Protocol no. SGNTUC-028)  
Principal Investigator: Dr Daphne Tsoi  
Opened to recruitment: March 2023

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BELLA: A Single Arm Phase II Trial Evaluating the Efficacy and Safety of Bevacizumab, Carboplatin, Gemcitabine and Atezolizumab in Early Relapsing Metastatic Triple Negative Breast Cancer  
Principal Investigator: Dr Daphne Tsoi  
Opened to recruitment: March 2023

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HERTHENA-Lung02 A Phase 3, Randomised, Open-label Study of Patritumab Deruxtecan Versus Platinum-based Chemotherapy in Metastatic or Locally Advanced Epidermal Growth Factor Receptor-mutated (EGFRm) Non-small Cell Lung Cancer (NSCLC) After Failure of Epidermal Growth Factor Receptor (EGFR) Tyrosine Kinase Inhibitor (TKI) Therapy (U31402-A-U301)  
Principal Investigator: A/Prof Timothy Clay  
Opened to recruitment: November 2022

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NAV-1003: A Phase 1 Study of the SHP2 Inhibitor BBP-398 (Formerly Known as IACS-15509) in Combination with the KRAS-G12C Inhibitor Sotorasib in Patients with Advanced Solid Tumors and a KRAS-G12C Mutation  
Principal Investigator: A/Prof Timothy Clay  
Opened to recruitment: November 2022

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PICCOLO: A Phase 2, Single Arm Study of Mirvetuximab Soravtansine in Recurrent Platinum-Sensitive, High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression  
Principal Investigator: Dr Andrew Dean  
Opened to recruitment: July 2022

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KEYNOTE-C93: A Phase 3 Randomised, Open-label, Active-comparator Controlled Clinical Study of Pembrolizumab versus Platinum Doublet Chemotherapy in Participants With Mismatch Repair Deficient (dMMR) Advanced or Recurrent Endometrial Carcinoma in the First-line Setting (GOG-3064/ENGOT-en15)  
Principal Investigator: Dr Tarek Meniawy  
Opened to recruitment: June 2022

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ASCEND: A Randomised, Double-Blinded Phase II Study of Gemcitabine and Nab-Paclitaxel with CEND-1 or Placebo in Patients with Untreated Metastatic Pancreatic Ductal Adenocarcinoma. (Protocol no. CTC0304/AG0121PC)  
Principal Investigator: Dr Andrew Dean  
Opened to recruitment: May 2022

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**Clinical trials active during FY22-FY24  
(currently active and closed to recruitment)**

AM ATX101-03: Phase 1b/2a Study Investigating ATX-101 In Combination With Platinum-Based Chemotherapy In Platinum-Sensitive, Recurrent Ovarian, Fallopian Tube and Primary Peritoneal Cancer  
Principal Investigator: Dr Tarek Meniawy  
Opened to recruitment: June 2022

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MK-3475-B96: A Phase 3, Randomised, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Paclitaxel with or Without Bevacizumab for the Treatment of Platinum-Resistant Recurrent Ovarian Cancer  
Principal Investigator: Dr Andrew Dean  
Opened to recruitment: June 2022

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CodeBreak101: A Phase 1b/2, Master Protocol Evaluating the Safety, Tolerability, Pharmacokinetics, and Efficacy of Sotorasib (AMG 510) in Subjects with Advanced Solid Tumors with KRAS p.G12C Mutation  
Principal Investigator: A/Prof Timothy Clay  
Opened to recruitment: February 2022

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ACE-Breast-03: A Global, Phase 2 Study Of ARX788 in HER2- positive Metastatic Breast Cancer Patients Whose Disease is Resistant or Refractory To T-DM1, and/or T-DXd, and/or Tucatinib-Containing Regimens  
Principal Investigator: Dr Daphne Tsoi  
Opened to recruitment: February 2022

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M14-239: Phase 2, Open-Label Safety and Efficacy Study of Telisotuzumab Vedotin (ABBV-399) in Subjects with Previously Treated c-Met+ Non-Small Cell Lung Cancer  
Principal Investigator: A/Prof Timothy Clay  
Opened to recruitment: January 2022

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ASCOLT: Aspirin for Dukes C And High Risk Dukes B Colorectal Cancers - An International, Multicentre, Doubleblind, Randomised Placebo Controlled Phase III Trial  
Principal Investigator: Dr Tom van Hagen  
Opened to recruitment: August 2014

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**DESTINY-Breast12:** An Open Label, Two Parallel Cohorts, Multinational, Multicenter, Phase 3b/4 Study of T-DxD (trastuzumab Deruxtecan) in Patients with or Without Baseline Brain Metastasis with Previously Treated Advanced/Metastatic HER2 Positive Breast Cancer (Protocol no. D9673C00007/254020)

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: January 2022

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**MK-4280A-007:** A Phase 3 study of MK-4280A (Coformulated Favezelimab [MK-4280] Plus Pembrolizumab [MK-3475]) Versus Standard of Care in Previously Treated Metastatic PD-L1 Positive Colorectal Cancer

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: December 2021

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**VICTOR:** A Pivotal Phase 3 Randomised, Placebo-controlled Clinical Study to Evaluate the Efficacy and Safety of the sGC Stimulator Vericiguat/MK-1242 in Adults with Chronic Heart Failure with Reduced Ejection Fraction

Principal Investigator: Dr Brendan McQuillan

Opened to recruitment: November 2021

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**DESTINY-Lung02:** A Phase 2, Multicenter Randomised Study of Trastuzumab Deruxtecan in Subjects with HER2 Mutated Metastatic Non-Small Cell Lung Cancer (NSCLC)

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: May 2021

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**HERTHENA-Lung01:** A Phase 2 Randomised Open-Label Study of Patritumab Deruxtecan (U3-1402) in Subjects with Previously Treated Metastatic or Locally Advanced EGFR-mutated Non-Small Cell Lung Cancer (NSCLC)

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: May 2021

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**AMPLITUDE:** A Phase 3 Randomised, Placebo-controlled, Double-blind Study of Niraparib in Combination with Abiraterone Acetate and Prednisone Versus Abiraterone Acetate and Prednisone for the Treatment of Participants with Deleterious Germline or Somatic Homologous Recombination Repair (HRR) Gene-Mutated Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: May 2021

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**INTEGRATE II:** A Randomised phase III Double-blind Placebo-Controlled Study of Regorafenib In Refractory Advanced Gastro-oesophageal Cancer (AGOC)

Principal Investigator: Dr Tom van Hagen

Opened to recruitment: May 2021

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**DESTINY-Breast05:** A Phase 3, Multicenter, Randomised, Open-Label, Active-Controlled Study Of Trastuzumab Deruxtecan (T-DXd) Versus Trastuzumab Emtansine (T-DM1) In Subjects With High-Risk HER2-Positive Primary Breast Cancer Who Have Residual Invasive Disease In Breast Or Axillary Lymph Nodes Following Neoadjuvant Therapy

Principal Investigator: Dr Daphne Tsoi

Opened to recruitment: April 2021

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**CLXH254C12201:** A Randomised, Open-Label, Multi-Arm, Two Part, Phase II Study To Assess The Efficacy And Safety Of Multiple LXH254 Combinations In Patients With Previously Treated Unresectable Or Metastatic BRAFV600 or NRAS Mutant Melanoma

Principal Investigator: Dr Tarek Meniawy

Opened to recruitment: April 2021

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**NAVIGATE: A Phase 2 Basket Study of the Oral TRK Inhibitor larotrectinib in Subjects with NTRK Fusion-Positive Tumors**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: March 2021

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**DUO-E: A Randomised, Multicenter, Double-blind, Placebo-controlled, Phase III Study of First-line Carboplatin and Paclitaxel in Combination with Durvalumab, Followed by Maintenance Durvalumab with or without Olaparib in Patients with Newly Diagnosed Advanced or Recurrent Endometrial Cancer**

Principal Investigator: Dr Tarek Meniawy

Opened to recruitment: December 2020

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**BGB-900-105: Phase 1/1b Study Investigating Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of Anti-TIGIT Monoclonal Antibody BGB-A1217 in Combination with Anti-PD-1 Monoclonal Antibody Tislelizumab (BGB-A317) in Patients with Unresectable Locally Advanced or Metastatic Solid Tumors**

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: December 2020

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**SORAYA: A Phase 3, Single Arm Study of Mirvetuximab Soravtansine in Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: November 2020

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**SKYSCRAPER-07: A Phase III, Randomised, Double-Blind, Placebo-Controlled Study of Atezolizumab With or Without Tiragolumab (Anti-Tigit Antibody) In Patients with Unresectable Oesophageal Squamous Cell Carcinoma Whose Cancers Have Not Progressed Following Definitive Concurrent Chemoradiotherapy**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: October 2020

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**ORIENT-15: A Multicenter, Double-Blind, Randomised Phase 3 Clinical Trial Evaluating the Efficacy and Safety of Sintilimab vs. Placebo, in Combination with Chemotherapy, for First-Line Treatment of Unresectable, Locally Advanced, Recurrent, or Metastatic Esophageal Squamous Cell Carcinoma**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: October 2020

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**SER 301: A Seamless Phase 1b Study to Evaluate Safety, Tolerability and Efficacy of SER-301 in Adult Subjects with Active Mild-to-Moderate Ulcerative Colitis**

Principal Investigator: Prof Ian Lawrance

Opened to recruitment: September 2020

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**NAPOLI 3: An Open-Label, Randomised, Multicenter, Phase III Study Of Irinotecan Liposome Injection, Oxaliplatin, 5-Fluorouracil/Leucovorin Versus Nab-Paclitaxel Plus Gemcitabine In Subjects Who Have Not Previously Received Chemotherapy For Metastatic Adenocarcinoma Of The Pancreas**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: July 2020

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**QUASAR: A Phase 2b/3, Randomised, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Efficacy and Safety of Guselkumab in Participants with Moderately to Severely Active Ulcerative Colitis (CNT01959UCO3001)**

Principal Investigator: Prof Ian Lawrance

Opened to recruitment: July 2020

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**PROOF: A Phase 3 Multicenter, Open-Label, Randomised, Controlled Study of Oral Infigratinib Versus Gemcitabine With Cisplatin in Subjects With Advanced/Metastatic or Inoperable Cholangiocarcinoma With FGFR2 Gene Fusions/Translocations**  
Principal Investigator: Dr Andrew Dean  
Opened to recruitment: December 2019

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**COSMIC-313: A Randomised, Double-Blind, Controlled Phase 3 Study of Cabozantinib in Combination with Nivolumab and Ipilimumab versus Nivolumab and Ipilimumab in Subjects with Previously Untreated Advanced or Metastatic Renal Cell Carcinoma of Intermediate or Poor Risk (Protocol XL184-313)**  
Principal Investigator: A/Prof Timothy Clay  
Opened to recruitment: October 2019

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**GO40558: A Phase II, Open-Label, Multicenter, Randomised Study Of The Efficacy And Safety Of RO7198457 In Combination With Pembrolizumab Versus Pembrolizumab In Patients With Previously Untreated Advanced Melanoma**  
Principal Investigator: Dr Tarek Meniawy  
Opened to recruitment: September 2019

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**BR.31: A Phase III Prospective Double Blind Placebo Controlled Randomised Study Of Adjuvant MEDI4736 In Completely Resected Non-Small Cell Lung Cancer**  
Principal Investigator: A/Prof Timothy Clay  
Opened to recruitment: June 2019

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**DESTINY 2: A Phase 3, Multicenter, Randomised, Open-Label, Active-Controlled Study Of DS-8201a, An Anti-HER2-Antibody Drug Conjugate, Versus Treatment Of Investigator's Choice For HER2-Positive, Unresectable And/Or Metastatic Breast Cancer Subjects Pretreated With Prior Standard Of Care HER2 Therapies, Including T-DM1 (DS-8201-A-U301)**  
Principal Investigator: Dr Daphne Tsoi  
Opened to recruitment: May 2019

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**DESTINY 3: A Phase 3, Multicenter, Randomised, Open-Label, Active-Controlled Study of DS-8201A, an Anti-HER2-Antibody Drug Conjugate, Versus Ado-Trastuzumab Emtansine (T-DM1) for HER2-Positive, Unresectable and/or Metastatic Breast Cancer Subjects Previously Treated with Trastuzumab and Taxane (DS-8201-A-U302)**  
Principal Investigator: Dr Daphne Tsoi  
Opened to recruitment: April 2019

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**TACTI-002 (Two ACTIVE Immunotherapeutics): A Multicenter, Open Label, Phase II Study In Patients With Previously Untreated Unresectable or Metastatic Non-Small Cell Lung Cancer (NSCLC), or Recurrent PD-X Refractory NSCLC or With Recurrent or Metastatic Squamous Head And Neck Cancer (HNSCC) Receiving the Soluble LAG-3 Fusion Protein Eftilagimod Alpha (IMP321) in Combination With Pembrolizumab (PD-1 Antagonist)**  
Principal Investigator: A/Prof Timothy Clay  
Opened to recruitment: February 2019

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**ATHENA: A Multicenter, Randomised, Double-Blind, Placebo-Controlled Phase 3 Study in Ovarian Cancer Patients Evaluating Rucaparib and Nivolumab as Maintenance Treatment Following Response to Front-Line Platinum-Based Chemotherapy**  
Principal Investigator: Dr Andrew Dean  
Opened to recruitment: December 2018

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**KEYNOTE- 826: A Phase 3 Randomised, Double-Blind, Placebo-Controlled Trial of Pembrolizumab (MK-3475) Plus Chemotherapy Versus Chemotherapy Plus Placebo for the First-Line Treatment of Persistent, Recurrent, or Metastatic Cervical Cancer**  
Principal Investigator: Dr Andrew Dean  
Opened to recruitment: November 2018

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**iPRIME: A Phase II Study Of Durvalumab (MEDI4736) And Tremelimumab In Combination With Neoadjuvant Carboplatin And Paclitaxel In Newly Diagnosed Women With Advanced High Grade Serous Ovarian, Fallopian Tube And Peritoneal Cancers**

Principal Investigator: Dr Tarek Meniawy

Opened to recruitment: October 2018

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**KEYNOTE-775: A Multicenter, Open-label, Randomised, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination with Pembrolizumab Versus Treatment of Physician's Choice in Participants with Advanced Endometrial Cancer**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: September 2018

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**ACTICCA-1: Adjuvant Chemotherapy With Gemcitabine and Cisplatin Compared to Standard of Care After Curative Intent Resection of Cholangiocarcinoma and Muscle Invasive Gallbladder Carcinoma**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: August 2018

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**EMPOWER-Cervical-1: An Open-Label, Randomised, Phase 3 Clinical Trial of REGN2810 Versus Investigator's Choice of Chemotherapy in Recurrent or Metastatic Cervical Carcinoma**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: February 2018

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**NIVO PASS: Pattern of Use and Safety/Effectiveness of Nivolumab in Routine Oncology Practice (CA209234)**

Principal Investigator: A/Prof Timothy Clay

Opened to recruitment: October 2017

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**PISCES OMS-II03: A Multicenter Phase 2, Open-label Trial of Intratumoral pIL-12 Plus Electroporation in Combination with Intravenous Pembrolizumab in Patients with Stage III/IV Melanoma who are Progressing on Either Pembrolizumab or Nivolumab Treatment (Keynote-695)**

Principal Investigator: Dr Tom van Hagen

Opened to recruitment: September 2017

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**Monarch E: A Randomised, Open-Label, Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer**

Principal Investigator: Dr Daphne Tsoi

Opened to recruitment: August 2017

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**VELIA: A Phase 3, Placebo-Controlled Study of Carboplatin/Paclitaxel with or without Concurrent and Continuation Maintenance Veliparib (PARP Inhibitor) in Subjects with Previously Untreated Stages III or IV High-Grade Serous Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (M13-694)**

Principal Investigator: Dr Andrew Dean

Opened to recruitment: August 2016

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**MONARCH 2: A Randomised, Double-Blind, Placebo-Controlled, Phase 3 Study Of Fulvestrant With Or Without LY22835219, A CDK4/6 Inhibitor, For Women With Hormone Receptor Positive, HER2 Negative Locally Advanced Or Metastatic Breast Cancer**

Principal Investigator: Dr Daphne Tsoi

Opened to recruitment: March 2015

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**POSITIVE: Pregnancy Outcome And Safety Of Interrupting Therapy For Women With Endocrine Responsive Breast Cancer**

Principal Investigator: A/Prof Timothy

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**SOFT: A Phase III Trial Evaluating the Role of Ovarian Function Suppression and the Role of Exemestane as Adjuvant Therapies for Premenopausal Women with Endocrine Responsive Breast Cancer**

Principal Investigator: Dr Daphne Tsoi

Opened to recruitment: March 2005

# Research Governance

Research Governance is a framework that ensures research is conducted responsibly, ethically, and safely. It is the responsibility of multiple stakeholders within an institution, the individual researchers, Clinical Trials staff, and Research Department staff to comply with these requirements.

Due to the changing landscape of research conduct, SJG Subiaco Hospital established a Research Governance Committee in June 2023. Its members comprise of the Director of Research, Director of Medical Services, Research and Clinical Trial Managers, Director of Nursing, Clinicians, Chief Pharmacist and Group Director of Research.

The Research Governance Committee (RGC) at Subiaco Hospital ensures compliance with the organisation's mission in several key ways:

- Review of research proposals. The RGC views all clinical trials and research proposals to ensure they are reflective of St John of God Health Care's Mission. This allows them to assess whether proposed research aligns with the organisation's values and goals.
- Resource and capacity assessment. When considering research proposals, the RGC evaluates the resources and capacity required. This helps ensure that approved research can be conducted effectively while maintaining St John of God Health Care's commitment to quality care and service.
- Alignment with Catholic teaching. As a ministry of the Catholic Church, SJG Subiaco Hospital operates within a framework set by Church teaching. The RGC considers whether research proposals are consistent with Catholic ethical standards and teachings.
- Ethical business practices. SJG Subiaco Hospital has a commitment to socially responsible and ethical business practices. The RGC ensures that research partnerships and collaborations adhere to these principles, including compliance with labour laws, discrimination laws, workplace safety, and environmental stewardship.
- Community benefit. Part of SJG Subiaco Hospital's Mission involves enhancing community wellbeing. The RGC may prioritise research that has potential benefits for the broader community, aligning with the hospital's commitment to corporate citizenship and community participation.
- Continuation of healing mission. The RGC likely favours research that supports the organisation's goal of continuing the healing mission of Jesus Christ by enhancing physical, intellectual, social and spiritual wellbeing.
- Ongoing monitoring. The RGC oversees the conduct of research and clinical trials throughout their durations, by reviewing related clinical incidents, annual progress reports and final reports.

By carefully assessing research proposals through these lenses, the RGC works to ensure that all research conducted under SJOG's auspices aligns with and furthers the organisation's Mission and Values.

To date, the Subiaco RGC has successfully reviewed 70 clinical trials and research proposals, and 172 annual progress and final reports.

# Additional Publications 2022-2024

## Anaesthesia & Pain

Toner AJ, Bailey MA, Schug SA, Phillips M, Ungerer JP, Somogyi AA, Corcoran TB: Serum lidocaine (lignocaine) concentrations during prolonged perioperative infusion in patients undergoing breast cancer surgery: A secondary analysis of a randomised controlled trial. *Anaesth Intensive Care* 2023, 51(6):422-431. <https://doi.org/10.1177/0310057X231194833>

Corcoran TB, Martin C, O'Loughlin E, Ho K, Chan M, Forbes A, Leslie K, Myles P: Dexamethasone and persistent wound pain: a prespecified analysis of the randomised Perioperative Administration of Dexamethasone and Infection (PADDI) trial. *Br J Anaesth* 2023, 131(1):93-103. <https://doi.org/10.1016/j.bja.2023.03.031>

Gibbs N, Preuss J, Matzelle S, Hansen A, Weightman W: Prediction of hypofibrinogenaemia based on the starting fibrinogen and extent of haemodilution during cardiac surgery. *Anaesthesia and Intensive Care*, 2022, In Press. <https://doi.org/10.1177/0310057X221138113>

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## Colorectal Cancer

Fernando D, Hanna J, Cohen R, Ryan J. Adjuvant chemotherapy improves survival amongst octogenarians following resection of colorectal adenocarcinoma. *ANZ J Surg* 2024 Feb;94(1-2):181-186, <https://doi.org/10.1111/ans.18715>

Cohen R, Platell CF. Metachronous colorectal cancer metastasis: Who, what, when and what to do about it. *J Surg Oncol* 2024, 129(1): 71-77. <https://doi.org/10.1002/jso.27400>

Cohen R, Platell CF, McCoy MJ, Meehan K, Fuller K. Circulating tumour DNA in colorectal cancer management. *Br J Surg* 2023. 110(7), 773-783. <https://doi.org/10.1093/bjs/znad126>

To YH, Degeling K, McCoy M, Wong R, Jones I, Dunn C, Hong W, Loft M, Gibbs P, Tie J. Real-world adjuvant chemotherapy treatment patterns and outcomes over time for resected stage II and III colorectal cancer. *Asia Pac J of Clin Oncol* 2023, 19(3):392-402. <https://doi.org/10.1111/ajco.13885>

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## Gynaecological Cancer

Hardcastle, S. J., Maxwell-Smith, C., Cavalheri, V., Boyle, T., Román, M. L., Platell, C., Levitt, M., Saunders, C., Sardelic, F., Nightingale, S., McCormick, J., Lynch, C., Cohen, P. A., Bulsara, M., & Hince, D. The promoting physical activity in regional and remote cancer survivors (PPARCS) trial: Physical activity maintenance. *Scandinavian Journal of Medicine & Science in Sports* 2024, 34(3), e14572. Article e14572. <https://doi.org/10.1111/sms.14572>

Kelly, S. M., Quenby, M., Corcoran, T. B., Webb, S., & Cohen, P. A. Variation in prescribing for the prevention of postoperative nausea, vomiting, and pain following abdominal surgery: A retrospective study. *Health Science Reports* 2024, 6(6), Article e1335. <https://doi.org/10.1002/hsr2.1335>

Schofield, C., Lopez, P., Cohen, P. A., Taaffe, D. R., Newton, R. U., Galvão, D. A., Jeffery, E., Meniawy, T. M., & Peddle-McIntyre, C. J. Skeletal muscle morphology in patients receiving primary versus interval cytoreductive surgery for advanced high-grade serous ovarian cancer. *International Journal of Gynecological Cancer* 2023, 33(10), 1587-1594. Article ijgc-2023-004425.  
<https://doi.org/10.1136/ijgc-2023-004425>

Cabasag, C. J., Arnold, M., Rutherford, M., Ferlay, J., Bardot, A., Morgan, E., Butler, J., O'Connell, D. L., Nelson, G., Høgdall, C., Schnack, T., Gavin, A., Elwood, M., Hanna, L., Courley, C., De, P., Saint-Jacques, N., Mørch, L. S., Woods, R. R., ... Soerjomataram, I. Shifting incidence and survival of epithelial ovarian cancer (1995-2014): a SurvMark-2 study. *International Journal of Cancer* 2023, 152(9), 1763-1777.  
<https://doi.org/10.1002/ijc.34403>

kConFab Investigators, & NBCS Collaborators. FANCM missense variants and breast cancer risk: a case-control association study of 75,156 European women. *European Journal of Human Genetics* 2023, 31(5), 578-587.  
<https://doi.org/10.1038/s41431-022-01257-w>

Schofield, C., Newton, R. U., Taaffe, D. R., Galvão, D. A., Cohen, P. A., Meniawy, T. M., & Peddle-McIntyre, C. J. Supervised resistance exercise for women with ovarian cancer who have completed first-line treatment: a pragmatic study. *Supportive Care in Cancer* 2023, 31(5), 304. Article 304.  
<https://doi.org/10.1007/s00520-023-07754-y>

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