

FISCAL YEAR 2022-2023

Annual Research Report



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Year in Review: Unveiling Highlights in Research Excellence

With tremendous enthusiasm, I present the Annual Research Report for the Capital, Coast, and Hutt Valley district. During the previous year, notable achievements were made by our Research Office (RO) and Clinical Trials Unit (CTU), which also introduced modifications aimed at strengthening our dedication to the progression of healthcare in our district. The resource optimisation achieved through the reorganisation process initiated by the RO and CTU has significantly aided in the support of research undertakings.

Our dedication to fostering effective governance and collaboration has been exemplified by initiatives such as re-configuring the Research Governance Committee and advancing substantial consultation with Māori regarding research affairs. Despite the challenges faced, the Interim Research Advisory Group – Māori (IRAG-M) sparked a renewed approach that emphasizes community engagement and culturally sensitive research methodologies. The successful migration of our Research Registry to the REDCap database represents a noteworthy accomplishment for the current year. In addition to consolidating research documents, this migration also optimised critical prerequisites such as documents pertaining to Māori endorsement, ethics approval, and locality approval. This innovative system serves as a model of effectiveness, guaranteeing dependable and succinct documentation while accelerating the succession from submitting a research proposal to disseminating findings.

In light of the continuous transformations, our primary objective continues to be the empowerment of our research teams. By means of dynamic seminars, trainings, and advanced research registries, we furnish our teams with the necessary resources and expertise to effectively respond to changing circumstances and uphold elevated benchmarks in research. Our commitment to accomplishing impactful and inclusive research is exemplified by our ongoing training programmes, innovative partnerships with research institutes, and joint inquiries with universities concerning sustainable research methodologies. The forthcoming year exhibits potential for additional progress, more robust partnerships, and momentous revelations. Our organisation is committed to upholding our elevated benchmarks of excellence, inclusiveness, and ingenuity in our pursuits that to revolutionise healthcare results and confront pressing issues, with patients at the forefront of our focus.

I would like to extend my sincere appreciation to all those who have assisted and been dedicated to our accomplishments. We remain committed to impacting the trajectory of healthcare by employing contemporary methods of research.



Raulle Sol Cruz

Research Office and Clinical Trials Unit Manager
Capital & Coast and Hutt Valley Hospitals



(L-R) **April Dano**: Regulatory Advisor CCHV
Stephen Inns: Medical Lead-Research CCHV
Raulle Sol Cruz: Research Manager CCHV
Rhoze Sol Cruz: Clinical Nurse Specialist-Research CCHV
Michelle Bermudez: Research Office Administrator CCHV

Research Governance Committee Chair's Report

Kia ora koutou katoa,

It is my privilege to introduce the Annual Research Review for 2022-2023 at Capital Coast and Hutt Valley. It is now a year since I took up the post of Medical Lead for Research and with it Chair of the Research Governance Committee (RGC). This past year, our community has seen profound contributions and advancements that reflect the dedication and innovative spirit of our researchers, and those are reflected in this review.

This is the first review in 4 years and it has required numerous improvements in our data systems to produce. It is our intention to celebrate research in our organisation yearly in November in the future, so we will be in touch soon looking for your contributions for the 2023-24 review.

The re-establishment of the RGC has been pivotal, reinvigorated with a focus on enhancing governance and financial transparency. I thank the committee members who give up their time to improve research in our organisation.

In this edition, we feature just some of the outstanding research achievements of the Capital Coast and Hutt Valley team. Dr. Thomas Mules has been instrumental in enhancing gastroenterological research through his work at the Malaghan Institute and the completion of his PhD at the University of Otago. His thesis was placed on the Health Sciences Divisional List of Exceptional Doctoral theses. The List comprises only those Doctoral candidates whose research is assessed by examiners as being of an exceptional standard in every respect and amongst the top 10% of theses examined. I would like to personally congratulate him on this remarkable achievement.

We also celebrate the ground-breaking work of Dr. Rob Weinkove, who has led the ENABLE trial, New Zealand's first Chimeric Antigen Receptor (CAR) T-cell cancer therapy study. His efforts have brought forward a promising avenue for cancer treatment, highlighting our role on the global stage of medical research.

Finally, special acknowledgment is due to Dr. Daniel Frei on the completion of his PhD. His work on perioperative oxygen therapy has provided valuable insights that pave the way for future research in improving surgical outcomes.

As we celebrate these achievements, I encourage more clinicians to engage with research in our organisation. Please let us know about all your successes and be sure to seek our assistance where needed. Your involvement is crucial as we work to improve patient outcomes and uphold our commitment to innovation and excellence.

Ngā mihi,

Stephen Inns, MBChB, FRACP, MD(Res)

Chair, Research Governance Committee
Medical Lead for Research, Capital Coast and Hutt Valley



Introducing the Research Governance Committee



Stephen Inns
Medical Lead—Research CCHV



Raulle Sol Cruz
Research Manager CCHV



Tutangi Amataiti
Allied Professions Lead –
Pacific Peoples Health



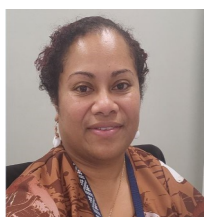
Carolyn Coles
Director of Midwifery CCHV



Maria Saito-Benz
Neonatologist



Cheryl Goodyer
Principal Advisor-Māori
IRAG-M representative



Agnes McKay
SCN/Clinical Lead-Pacific Health Unit



Susanna Every-Palmer
Forensic Psychiatrist Consultant



Hemakumar Devan
Physiotherapist



Daniel Frei
Specialist Anaesthetist



Phoenix Ahomiro
Nurse Coordinator-NETP



Saptarshi Mukerji
SMO– Emergency Department

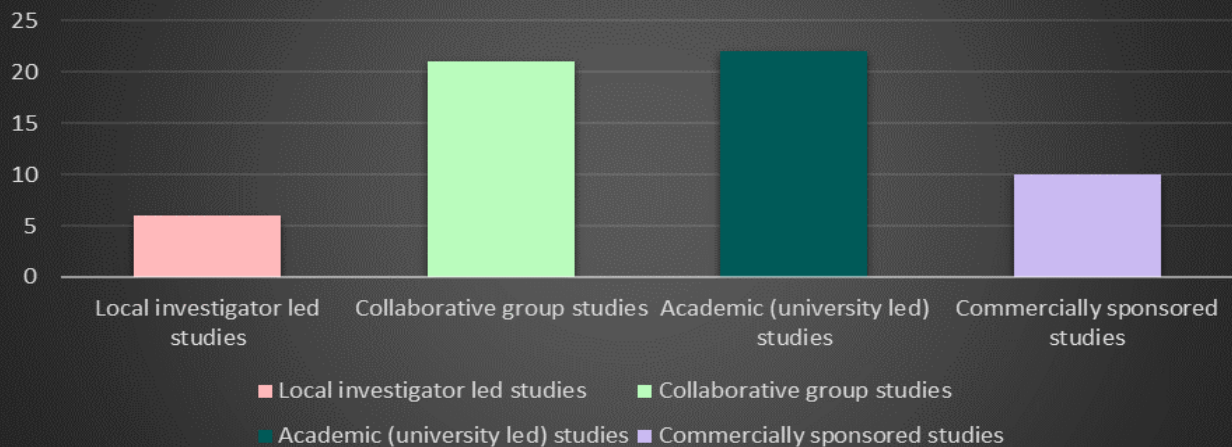
The Year in Retrospect

LOCALITY APPROVALS

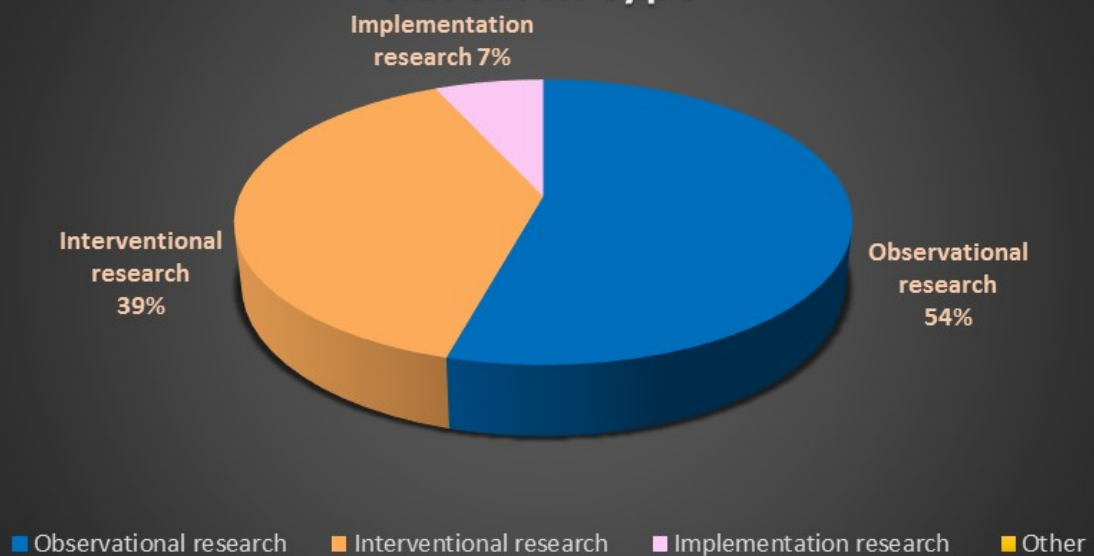
2022-23 saw strong research activity at Capital, Coast and Hutt Valley and the number of locality approvals processed reflects this. Many of our studies are in collaboration with University staff members but we have strong collaborative ties with national and international research groups as well as ongoing success in attracting commercially sponsored studies.

The majority of the research conducted is observational in nature but it is well balanced by interventional research including randomised controlled studies.

Project type



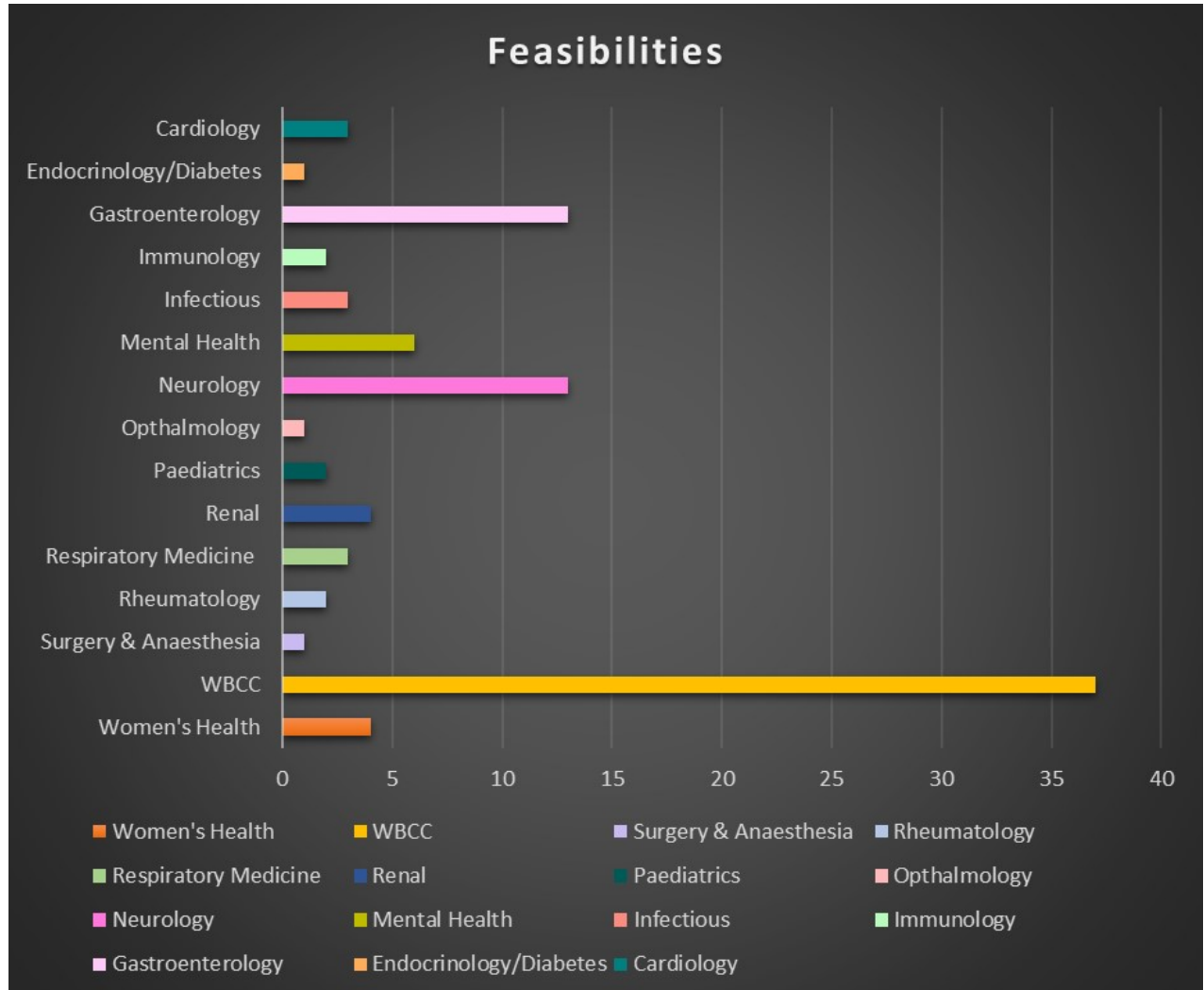
Research type





The Year in Retrospect

Feasibility Assessments



The feasibility assessment, facilitated by the Research Office, evaluates the practicality and viability of the proposed research project, considering resource availability, technical feasibility, timeline, risk assessment, ethical considerations, and stakeholder engagement. Not all assessments go on to site initiation but this metric gives an indication of the strength of our future research opportunities.

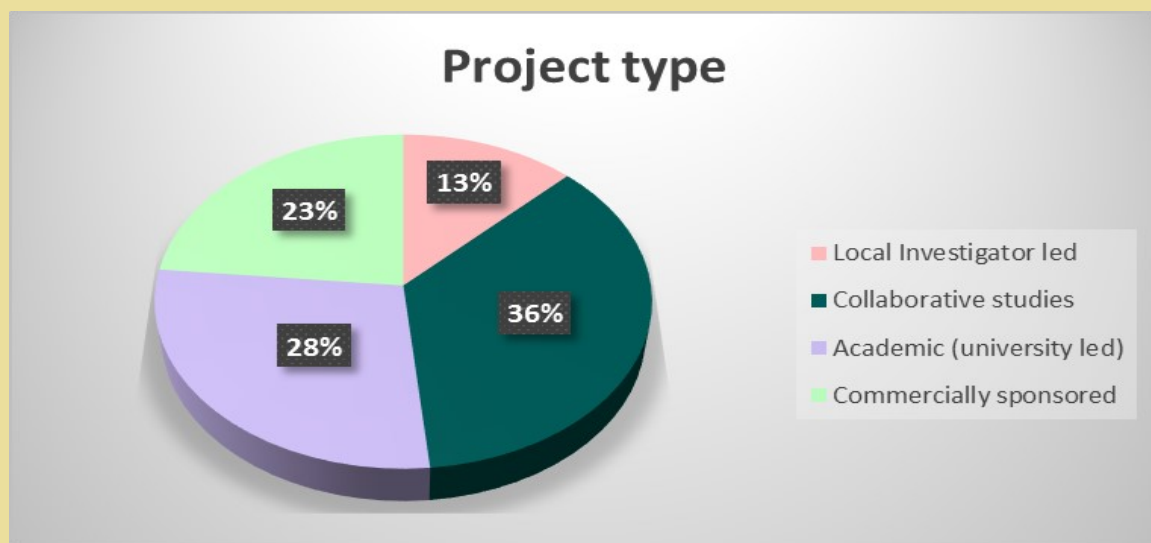
The Research Office is available to assist with feasibility questionnaires and we can work with researchers to ensure the resources needed to conduct a study are in place. We encourage clinicians to come to us with any feasibility approaches they receive.



The Year in Retrospect

Interim Research Advisory Group Māori

IRAG-M applications (65 applications)



The purpose of the Interim Research Advisory Group Māori (IRAG-M) is to provide a mechanism to engage representatives of the Māori community, to allow researchers to have their research proposals considered from a Māori perspective when seeking locality approval.

During the period of July 2022 to June 2023, the Interim Research Advisory Group-Māori (IRAG-M) evaluated 65 applications. Among these, collaborative studies constituted the highest proportion at 36%, followed by academic studies at 28%, commercially sponsored projects at 23%, and locally investigator-led studies at 13%.

Research Showcase

Significant milestone in first NZ CAR T-cell trial, run at Capital, Coast & Hutt Valley

New Zealand's first **Chimeric Antigen Receptor (CAR) T-cell cancer therapy** trial, **ENABLE**, run at Capital, Coast & Hutt Valley, recently completed treatment. Thanks to ENABLE, a phase 1 safety study, 30 patients with end-stage lymphomas received this new CAR T-cell therapy, manufactured at the Malaghan Institute of Medical Research.

Results from the first 21 patients treated with the new gene-modified immune cell treatment were presented by **Dr Rob Weinkove** at the prestigious American Society of Hematology meeting in December 2023.

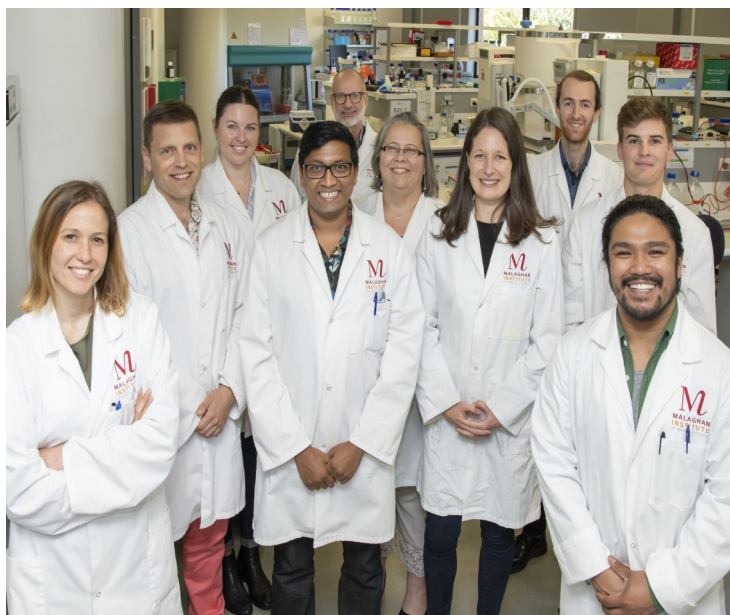
"The most remarkable finding in the ENABLE trial is the unusually low rate of two common side effects of CAR T-cell therapies – neurotoxicity and cytokine release syndrome – despite response rates similar to commercial treatments. The low toxicity has allowed us to treat patients without planned hospital admission, saving healthcare dollars," says Dr Weinkove.

"Some ENABLE trial participants, who had exhausted all lymphoma treatment options, have been in remission for over two years. Since then, we have treated a further nine patients – all as outpatients – with similarly promising results."

The Malaghan Institute is now planning a larger trial, **ENABLE-2**, to confirm effectiveness and safety of the CAR T-cell therapy. This phase 2 trial will treat up to 60 patients earlier in the course of their lymphoma, over two years.

"We hope to start enrolment to ENABLE-2 in quarter 2 of 2024. We are liaising with regulators, and we hope that ENABLE-2 will lead to routine CAR T-cell delivery in Aotearoa.

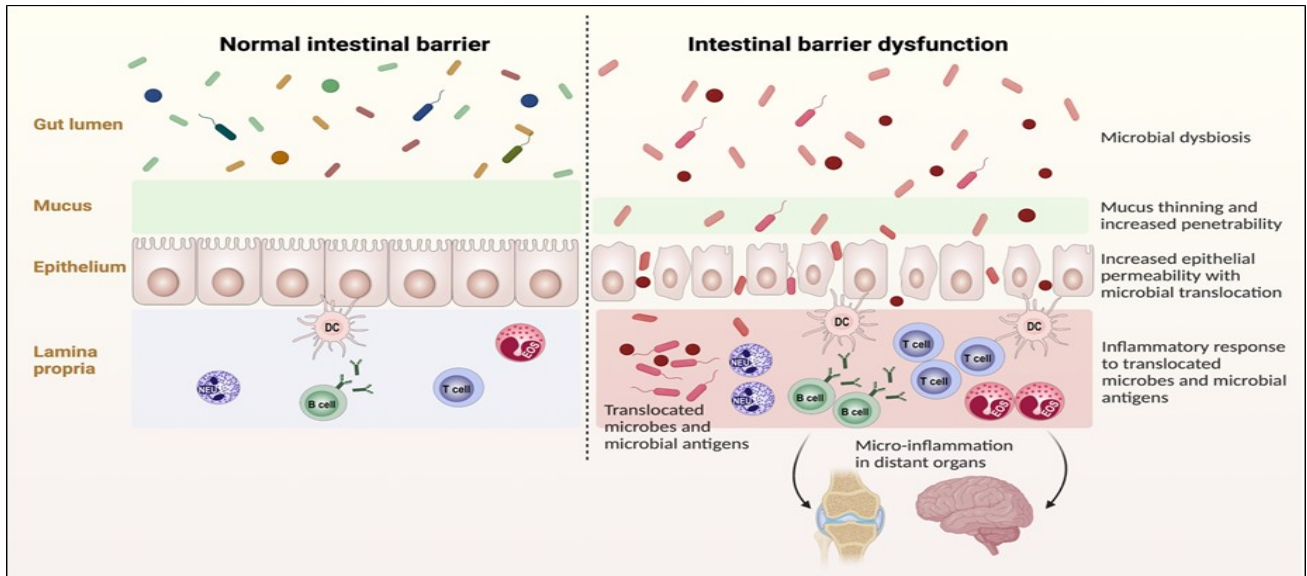
"Thanks to our colleagues in the Research Unit, on Ward 5 North and at Wellington Blood and Cancer Centre for their support and assistance in this ground-breaking trial programme – they can be proud to be part of New Zealand's first *CAR T-cell therapy*!"



Research Showcase

Dr. Thomas Mules, a recent PhD graduate and a gastroenterologist at Hutt Hospital, is at the forefront of research into the surge of gastrointestinal diseases. Tom's thesis, completed through the University of Otago, tackled the complex issue of why diseases like IBD and IBS are on the rise and how we might shift focus from treatment to prevention.

In his research, Tom investigated the "leaky" gut hypothesis, where a compromised intestinal barrier allows harmful substances to trigger inflammation and disease (see the figure below taken from his thesis). He delved into the potential of helminths, organisms we typically view as parasites, to strengthen this barrier and prevent disease.



Exposure to barrier-damaging agents impairs intestinal barrier function causing microbial translocation and inflammation, and contributes to disease development

His findings are a breakthrough, suggesting that these helminths could actually alleviate symptoms of gut hypersensitivity and may serve as a novel therapy for conditions such as ulcerative colitis. His pilot study on using controlled helminth infections in a clinical trial setting has laid the groundwork for larger trials, offering a new avenue for patient treatment.

On completing his thesis, Tom expressed that it was the most stimulating and fulfilling work of his career, marking a significant step forward in his research journey.

Tom's work encapsulates our research community's drive to explore and understand complex medical conditions. His PhD journey is an inspiration for both current and future researchers at our institution.

Congratulations to Tom on his exceptional work and the completion of his PhD.

Research Showcase



Daniel Frei's PhD Research on Perioperative Oxygen Therapy

Daniel Frei's PhD explored the optimal oxygen regimen during surgery, a critical issue given the universal use of oxygen in the more than 300 million surgeries conducted annually worldwide. His work reviewed existing literature on perioperative oxygen regimens, revealing a lack of definitive evidence to support liberal or conservative oxygen use.

Dan then surveyed specialist anaesthetists, finding varied beliefs and practices, with the majority titrating inspired oxygen levels to pulse oximetry readings they considered to be safe, despite the absence of consensus. His studies in ten metropolitan hospitals showed a generally intermediate approach to oxygen administration by anaesthetists. His retrospective analyses of over 15,000 patients showed potential benefits and risks associated with liberal perioperative oxygen administration. This study demonstrated an association between low inspired oxygen and increased surgical site infection rates, and increasing oxygen administration and increasing risk of respiratory complications and risk of admission to the intensive care unit.

Dan's research culminated in a multi-centre randomized feasibility trial, laying the groundwork for a definitive trial on perioperative oxygen therapy. The trial demonstrated the feasibility of conducting further research without major protocol modifications.

His findings highlight the need for a definitive trial to resolve ongoing uncertainties about perioperative oxygen therapy, aiming to optimize patient outcomes.



Research Department Spotlights



A Request: The following list of research contributions was obtained by a Pubmed literature search and through email correspondence with departmental research managers, clinical leads, and research nurses. In the course of this we discovered many contributions that did not include Health New Zealand in the author affiliations. It is important that the affiliations of authors in publications include *Health New Zealand Te Whatu Ora Capital Coast and Hutt Valley* so that we can celebrate our success.

Research Department Spotlights

ALLIED HEALTH



DR HEMAKUMAR DEVAN Physiotherapist	RESEARCH TOPIC Clinical academic in pain management	AWARD Early Career Award for Distinction in Research, University of Otago https://www.otago.ac.nz/wellington/about/news/early-career-researchers-committed-to-making-a-difference
SARAH MAJEED-GALE Oral Health Therapist		AWARD Te Tohu Ratonga Tūmatanui o Aotearoa New Zealand Public Service Day medal
LINDA WILLIAMS PhD candidate Dietitian	RESEARCH TOPIC Qualitative research exploring barriers and facilitators to accessing nutrition advice for women affected by endometrial cancer	AWARD Funding: Cancer society Professional Development Award (Travel Grant), Presentation Award: Oral Presentation – Runner Up. British Gynaecological Cancer Society Annual Scientific Meeting.
GRACE GRIFFITHS Hand Therapist/ Occupational Therapist	RESEARCH TOPIC Patient experiences of healthcare for upper limb Complex Regional Pain Syndrome	AWARD HRC Clinical Research Training Fellowship https://www.hrc.govt.nz/news-and-events/links-between-active-travel-and-health-be-studied-part-111m-awarded-nz-researchers
GILLIAN WATSON PhD Candidate Physiotherapist	RESEARCH TOPIC Physiotherapists' perspective of retention within Te Whatu Ora	AWARD HRC Clinical Research Training Fellowship https://www.hrc.govt.nz/resources/research-repository/physiotherapists-perspective-retention-within-te-whatu-ora

Research Department Spotlights

CLINICAL TRIALS UNIT

RAULLE SOL CRUZ— Research Manager
 DR KETNA PAREKH—SMO RESEARCH
 JONATHAN BARRETT— Charge Nurse Manager
 ANNE-MARIE KELL- Research Nurse
 JOAN PARAMA - Research Nurse
 ROSE ANN YAP - Research Nurse
 MAXINE MITCHELL - Research Nurse
 KELLY BARRETT— Data Manager
 NATASHA EAGLE- Research Coordinator
 VIOLA LASRADO—Research Assistant



STUDY	PRINCIPAL INVESTIGATOR	RESEARCH NURSE/ COORDINATOR
Abbvie_M16_066 (Gastro) Study of the Efficacy and Safety of Risankizumab in Subjects with Ulcerative Colitis.	Dr Ben Griffiths	Jonathan Barrett
Abbvie_M16_067 (Gastro) Evaluate the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Ulcerative Colitis	Dr Ben Griffiths	Jonathan Barrett
Abbvie-M20-370 (Rheumatology) Safety and Efficacy Study of ABBV-154	Dr Ketna Parekh	Jonathan Barrett
ABI-H0371-204 Study Evaluating Regimens Containing Vebicorvir in Subjects with Chronic Hepatitis B Virus Infection.	Dr Nigel Stace	Anne-Marie Kell
AIDA 304 (Gastro) Study of SHP647 in Subjects with Moderate to Severe Ulcerative Colitis or Crohn's Disease	Dr Ben Griffiths	Jonathan Barrett
Allegory (Rheumatology) Evaluate the efficacy and safety of Obinutuzumab in patients with systemic lupus erythematosus	Dr Ketna Parekh	Jonathan Barrett
Ascot (Infectious Disease) To Assess the Clinical, Virological and Immunological Outcomes in Patients with SARS-CoV-2 Infection (COVID-19).	Dr Nigel Raymond	Rose Ann Yap

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PARTICIPANTS ENROLLED

Research Department Spotlights

CLINICAL TRIALS UNIT

STUDY	PRINCIPAL INVESTIGATOR	RESEARCH NURSE/ COORDINATOR
Calliditas GSN000350 (Hepatobiliary) A Phase 2b Trial of Setanaxib in Patients with PBC and Elevated Liver Stiffness	Dr Amanda Chen	Anne-Marie Kell
Connect FX_Extension Study (Child Health) Study to Assess the Long-Term Safety and Tolerability of ZYN002 Administered as a Transdermal Gel to Children and Adolescents with Fragile X Syndrome	Dr Andrew Marshall	Natasha Eagle
Covid-Booster (Infectious Disease) Safety and Immunogenicity of BNT162b2 co administered With SIV in Adults 18 Through 64 Years.	Dr Tim Blackmore	Joan Parama
CP-4-006 (Child Health) 12 months, efficacy and safety study of weekly MOD-4023 compared to daily Genotropin® - therapy in pre-pubertal children with growth hormone deficiency	Dr Esko Wiltshire	Jonathan Barrett
Crossing (Gastro) A study to investigate changes in symptoms and esophageal histology with tezepelumab compared with placebo in patients aged 12 to 80 years old with eosinophilic esophagitis.	Dr Ben Griffiths	Jonathan Barrett
C-Steroid (Maternal Health) Corticosteroids before planned caesarean section from 35+0 to 39+6 weeks of pregnancy.	Dr Judy Ormandy	Hazel Irvine Rose Ann Yap
Embrace (Infectious Disease) Study to Assess the Efficacy, Safety and Immunogenicity of Vaccination With ExPEC9V in the Prevention of Invasive Extraintestinal Pathogenic Escherichia coli Disease in Adults Aged 60 Years And Older with a History of Urinary Tract Infection in the Past 2 Years	Dr Nigel Raymond	Anne-Marie Kell
Enanta (Child Health) Study to Evaluate EDP-938 Regimens in Subjects Aged 28 Days to 36 Months Infected With Respiratory Syncytial Virus (RSV)	Dr Torsten Stanley	Rose Ann Yap Natasha Eagle
Finch 4 (Rheumatology) Study to Assess the Safety and Efficacy of Filgotinib in Subjects with Rheumatoid Arthritis.	Dr Ketna Parekh	Anne-Marie Kell
Grace (Maternal and Child Health) A Phase III double-blind study to assess safety and efficacy of an RSV Maternal unadjuvanted vaccine, in pregnant women and infants born to vaccinated mothers.	Dr Judy Ormandy Dr Torsten Stanley	Rose Ann Yap Natasha Eagle
Lighthouse II (Neurology) Phase 3 Trial Of Triumeq In Amyotrophic Lateral Sclerosis.	Dr. Purva Joshi	Joan Parama
Lum-201-01 (Child Health) Study of Daily Oral LUM-201 in Naïve-to-Treatment, Prepubertal Children with Idiopathic Growth Hormone Deficiency (GHD)	Dr Esko Wiltshire	Jonathan Barrett
Matisse (Maternal and Child Health) Evaluate the Efficacy and Safety of RSVpreF in Infants Born to Women Vaccinated During Pregnancy.	Dr Judy Ormandy Dr Torsten Stanley	Rose Ann Yap Natasha Eagle
Melody (Child Health) Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants.	Dr Torsten Stanley	Rose Ann Yap
MK1654 (Child Health) Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of MK-1654 in Infants and Children at Increased Risk for Severe RSV Disease	Dr Torsten Stanley	Rose Ann Yap Natasha Eagle
M20-371 (Gastro) Study to Evaluate the Safety and Efficacy of ABBV-154 in Subjects with Moderately to Severely Active Crohn's Disease (CD): AIM-CD.	Dr Ben Griffiths	Jonathan Barrett
Nash INC 747-304 Study to Evaluate the Efficacy and Safety of Obeticholic Acid in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis.	Dr Nigel Stace	Anne-Marie Kell
Oasis (Infectious Disease) study to evaluate the efficacy and safety of olorofim versus AmBisome® for treatment of invasive aspergillosis (IA).	Dr Olivia Bupha-Intr	Jonathan Barrett Natasha Eagle
Ohand (Neurology) Study to evaluate the efficacy and safety of ocrelizumab in adults with primary progressive multiple sclerosis	Dr Jenny Taylor	Anne-Marie Kell
Penguin1 (Rheumatoid) Study to Evaluate the Efficacy and Safety of Filgotinib in Subjects with Active Psoriatic Arthritis Who Are Naïve to Biologic DMARD Therapy	Dr Ketna Parekh	Joan Parama
REV-C (Child Health) To Evaluate the Safety, Tolerability, Pharmacokinetics and Antiviral Effect of RV521 (REVIRAL 1)	Dr Torsten Stanley	Rose Ann Yap
RSV-MAT-15 (Maternal Health) A follow-up study to describe the safety of study participants who received RSVPreF3 maternal vaccination (any dose) or controls from previous RSV MAT studies during any pregnancy conceived post vaccination/control.	Dr Judy Ormandy	Rose Ann Yap Natasha Eagle
SER-301-001 Study to Evaluate Safety, Tolerability and Efficacy of SER-301 in Adult Subjects with Active Mild-to-Moderate Ulcerative Colitis	Dr Ben Griffiths	Jonathan Barrett
T2Now (Child Health) Evaluating the Safety and Efficacy of Dapagliflozin 5 and 10 mg, and Saxagliptin 2.5 and 5 mg in Pediatric Patients with Type 2 Diabetes Mellitus Who Are Between 10 and Below 18 Years of Age	Dr Esko Wiltshire	Jonathan Barrett

Research Department Spotlights

CARDIOLOGY HUTT VALLEY HOSPITAL

HEART-FID TRIAL COMPLETED

<https://www.escardio.org/The-ESC/Press-Office/Press-releases/Iron-therapy-linked-with-reduced-hospitalisation-in-iron-deficient-heart-failure-patients>



STUDY	PRINCIPAL INVESTIGATOR	RESEARCH NURSE/ COORDINATOR
VICTOR : A Study of Vericiguat (MK-1242) in Participants With Chronic Heart Failure With Reduced Ejection Fraction (HFrEF) (MK-1242-035)	Dr Katherine Ferrier	Jo-Anne Kovacs
Finearts-HF : Study to Evaluate the Efficacy (Effect on Disease) and Safety of Finerenone on Morbidity (Events Indicating Disease Worsening) & Mortality (Death Rate) in Participants With Heart Failure and Left Ventricular Ejection Fraction (Proportion of Blood Expelled Per Heart Stroke) Greater or Equal to 40%	Dr Katherine Ferrier	Jo-Anne Kovacs
Victorion-2 Prevent : Study of Inclisiran to Prevent Cardiovascular (CV) Events in Participants With Established Cardiovascular Disease	Dr Susan Plunkett	Jo-Anne Kovacs

Research Department Spotlights

CARDIOTHORACIC

- Member of University of Otago research Group led by Professor Ivan Sammut examining ischaemia reperfusion in hearts. This project is HRC funded awarded \$1,143,638.85 in 2020 for a duration of 42 Months.

A novel therapeutic to protect hearts in acute ischaemic procedures



- Since 2016 we have been collecting lung cancer tissues (primary and metastatic disease) and blood samples on patients undergoing thoracic resections and contributing these to the GMRI tissue bank

Lung Cancer Tissue Bank



- Working with the Professor Peter Larsen and member of the Wellington Cardiovascular Research Group a cardiac tissue collection study to examine inflammation in patients with cardiovascular disease and the changes in cardiac fibroblast following acute coronary syndromes.

ECCAD study (cardiac tissue collection in patients undergoing CABG)



- This will provide valuable information on the pathophysiology of CAD in patient cohorts relevant to Aotearoa New Zealand. It will also ensure that Māori patient samples are represented in modern datasets that are used for the continued improvement of coronary artery disease treatment.

Investigating the immune cell landscape in coronary artery disease



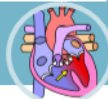
- Wellington Submitting to NZ registry and ANZSCTS registry
- Member (S Galvin) of Database Steering group of Cardiac Surgery database , Centre of Cardiovascular Research & Education in Therapeutics, School of Public Health and Preventive Medicine, Monash University

ANZSCTS Cardiac Surgery Database and NZ Cardiac Surgery Registry



- Recruiting centre and S Galvin member of Data Safety Monitoring Committee.
- The trial aims to compare the incidence of surgical site infection (and other healthcare associated infections), health economic and microbiological impact after intraoperative only (Arm A), to 24 hours (Arm B) and, to 48 hours (Arm C) of IV cefazolin and placebo postoperative surgical antimicrobial prophylaxis.

CALIPSO Trial



- Recruiting Centre and Investigators
- A phase III multicentre blinded randomised controlled clinical non-inferiority trial of cryopreserved platelets vs. conventional liquid-stored platelets for the management of post-surgical bleeding.
- The cryopreserved vs. liquid platelets trial

CLIP II



- John Riordan Cardiothoracic Surgeon Completing a Masters in patient safety at Oxford University

MSc patient Safety



- Dorothy Riddel Barnes Cardiothoracic CNS completing Masters in Nursing

Masters Nursing



- Dr Stephanine Ch'ng Cardiothoracic Surgeon awarded the prestigious James L. Cox Fellowship in Atrial Fibrillation Surgery to Visit Surgical departments in USA and Attend the AATS annual meeting as a travelling fellow in 2024.

American Association for Thoracic Surgery (AATS) Visiting Fellow



Research Department Spotlights

CARDIOLOGY WELLINGTON HOSPITAL

CARDIOLOGY TEAM

Bronwyn Davies , RN
Diane Middleditch, RN



STUDY	PRINCIPAL INVESTIGATOR	Research Nurse/ Coordinator
AEGIS-II: A Phase 3, Multicenter, Double-blind, Randomized, Placebo- controlled, Parallel-group Study to Investigate the Efficacy and Safety of CSL112 in Subjects with Acute Coronary Syndrome	Dr Scott Harding	Beverly Scott
ANZ-SCAD Registry: To describe the clinical, angiographic and intravascular imaging characteristics of a large Australian/NZ SCAD cohort	Dr Sarah Fairley	Bronwyn Davies
HBI 3000-402: A Phase 2, Two-Stage, Serial Cohort Dose Escalation and Expansion Study of a Single Intravenous Infusion of HBI-3000 for the Conversion of Atrial Fibrillation (AF) of Recent Onset	Dr Darren Hooks	Bronwyn Davies
PROTECT-ICD : Programmed Ventricular Stimulation to Risk Stratify for Early Cardioverter-Defibrillator (ICD) Implantation to Prevent Tachyarrhythmia following Acute Myocardial Infarction	Dr Matthew Webber	Beverly Scott

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PARTICIPANTS ENROLLED

Research Department Spotlights

CENTRE FOR ENDOCRINE, DIABETES & OBESITY RESEARCH

STUDY	PRINCIPAL INVESTIGATOR	RESEARCH NURSE/ COORDINATOR
He Rourou Whai Painga : A high quality Aotearoa New Zealand diet for metabolic health and whānau wellbeing	Prof. Jeremy Krebs	Rhiane Bishop
CORE Study : A randomised, double-blind, placebo-controlled, phase 3 study of ISIS 678354 administered subcutaneously to patients with severe hypertriglyceridemia.	Dr Rosemary Hall	Margaret Ward
Thyroid Eye Study : A phase 1, randomised, double-blind, placebo-controlled, single and multiple ascending dose study to determine the safety, tolerability, immunogenicity and pharmacokinetic properties of LASN01 in healthy subjects and in patients with pulmonary fibrosis or thyroid eye disease. <i>* only doing the thyroid eye disease part.</i>	Prof. Jeremy Krebs	Cecilia Ross

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PARTICIPANTS ENROLLED

CEDOR TEAM

Cecilia Ross, RN - Diabetes Research Projects Manager

Margaret Ward -Research RN

Amber Parry Strong- Research Fellow

Rhiane Bishop - Research Assistant



Health New Zealand
Te Whatu Ora

Research Department Spotlights

INTENSIVE CARE UNIT

WELLINGTON ICU RESEARCH TEAM

Dr. Paul Young—ICU Research Director

Dr. James Moore— Principal Investigator

Dr. David Golding— Research Fellow

Dr. Tak Chan— Research Fellow

Kelly Mc Causland— Research Administrator

Lean Navarra— ICU Research Manager

Kirsha Delaney— SCN Research

Reece Latonio— SCN Research

Eden Lesona— SCN Research

Joy Marmol— SCN Research

Shan Qui— SCN Research



Research Department Spotlights

INTENSIVE CARE UNIT

STUDY	PRINCIPAL INVESTIGATOR	Research Nurse/ Coordinator
AIRVO3 Automatic versus manual oxygen titration using a novel nasal high-flow oxygen delivery device in hospitalised adults in the ICU following elective cardiothoracic surgery	Dr Louis Kirton	Reece Latonio
BALANCE Multicentre, randomised, non-inferiority, concealed allocation trial of shorter duration (7days) vs longer duration (14 days) antibiotic treatment for patients with bloodstream infections admitted to hospital	Dr Paul Young	Kirsha Delaney Shan Qiu
BONANZA Multicentre, randomised, phase III trial of an improved neuro-intensive care management protocol guided by continuous brain tissue oxygen (PbtO2) monitoring, that aims to minimise cerebral hypoxia after severe traumatic brain injury (TBI).	Dr James Moore	Reece Latonio Shan Qiu
EPOTRAUMA Prospective, multi-centre, double-blind, phase III, randomised controlled trial to determine the effect of Epoetin Alfa on death and severe disability in critically ill trauma patients	Dr James Moore	Joradee Marmol Odessa David
MAGIC The trial is a two-sided superiority trial which will allocate patients with clinically significant vasoplegia in the ICU after cardiac surgery to methylene blue or placebo in a 1:1 ratio	Dr Paul Young	Reece Latonio Shan Qiu
MEGAROX This is designed to determine the effect of conservative oxygen therapy vs. liberal oxygen therapy on in-hospital mortality overall and also specifically in patients with: hypoxic ischaemic encephalopathy; acute brain pathologies (excluding hypoxic ischaemic encephalopathy); and sepsis	Dr Paul Young	Kirsha Delaney Joradee Marmol
REMAP CAP The primary objective of this REMAP is, for patients with severe CAP who are admitted to an ICU, to identify the effect of a range of interventions to improve outcome as defined by all-cause mortality at 90 days.	Dr Paul Young	Joradee Marmol Nina Roberts
SODABIC II The trial aims to assess if the infusion of 5% dextrose (D5W) + sodium bicarbonate, in vasopressor-dependent patients with moderate metabolic acidosis admitted to the ICU, increases the number of vasopressor-free hours at day 7, compared to the infusion of D5W alone.	Dr Paul Young	Kirsha Delaney Odessa David
SPICE IV The primary aim is to determine whether, in invasively mechanically ventilated patients who are ≥ 65 years of age, early sedation with DEX as the primary sedative agent reduces 90-day all-cause mortality.	Dr Paul Young	Kirsha Delaney Joradee Marmol
TARGET PROTEIN The primary hypothesis is that augmenting dietary protein to critically ill adult patients when compared to usual care will increase the number of days alive and out of the index hospital censored at day 90.	Dr Paul Young	Reece Latonio Shan Qiu

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PARTICIPANTS ENROLLED

Health New Zealand
Te Whatu Ora

Research Department Spotlights

NEONATAL INTENSIVE CARE UNIT (NICU)

Study	Principal Investigator	Research Nurse/Coordinator
PROTECT Pentoxifylline to PROTECT the preterm brain	Dr Maria Saito-Benz	Lisa Davie
PLUSS 2 The PLUSS Trial + Preventing Lung Disease using surfactant + steroid	Dr Callum Gately	Kat Carlyle
PEPI ARC Partnering Early to Provide for Infants at Risk of Cerebral Palsy	Dr Angelica Allermo Fletcher	Shannon Unka
NIRTURE Near Infra-Red spectroscopy targeted use to reduce adverse outcomes in extremely preterm infants.	Dr Maria Saito-Benz	Lisa Davie
NEOKANZ Neonatal Acute Kidney Injury in Australia and NZ Assess the incidence and risk factors for neonatal AKI in Aus/NZ neonatal intensive care (NICU) setting; Document nephrotoxin exposure as a modifiable risk factor for AKI in this population	Dr Angelica Allermo Fletcher	Lisa Davie



LISA DAVIE



SHANNON UNKA



KAT CARLYLE

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PARTICIPANTS ENROLLED

Research Department Spotlights

WELLINGTON BLOOD AND CANCER CENTRE

Mariska Van Essen—ACNM
Jennifer Dalen RN
Rachael Cahir RN
Ana Chariz Enriquez RN
Lourdjohn Geniston RN
Charisse Gleeson-Russo RN
Francois Lategan RN
Tess Ostapowicz RN
Debra Morriss RC
Tati Cocker RA



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PARTICIPANTS ENROLLED

Study	Principal Investigator	Research Nurse/Coordinator
ABBVIE 19-388 Extension rollover from M15-889: An Extension Study of Venetoclax for Subjects Who Have Completed a Prior Venetoclax Clinical Trial	Rob Weinkove	Debra Morriss
Alpine BGB B311-305: Randomized Study of Zanubrutinib (BGB 3111) Compared with Ibrutinib in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma	Rob Weinkove	Debra Morriss Jennifer Dalen
ASCEND (CML13): An ALLG single arm phase II study to evaluate the efficacy of asciminib in newly diagnosed patients with chronic phase chronic myeloid leukaemia	Alwyn D'Souza	Jennifer Dalen
BGB-11417-101: A Phase 1/1b Open-Label Dose Escalation and Expansion Study of Bcl-2 Inhibitor BGB-11417 in Patients with Mature B-Cell Malignancies.	Rob Weinkove	Charisse Gleeson LJ Geniston
BGB-11417-103: A Phase 1b/2, Open-Label, Dose Finding, and Expansion Study of the Bcl-2 Inhibitor BGB-11417 in Patients With Myeloid Malignancies	Travis Perera	LJ Geniston Francois Lategan
BGB- 3111-LTE: A Phase 3, Randomized Study of Zanubrutinib (BGB 3111) Compared with Ibrutinib in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma	Robert Weinkove	Debra Morriss
BMS CA209-8FC: A Randomized, Double-Blind, Parallel, Phase 1 Study to Compare the Pharmacokinetics of BMSCHO1-Nivolumab Process D to Nivolumab Process C after Complete Resection of Stage IIIa/b/c/d or Stage IV Melanoma.	Catherine Barrow	Francois Lategan
BMS Subcut Nivo Study: CA209-8KX – Phase I / II pharmacokinetic multi-tumour study of subcutaneous formulation of Nivolumab monotherapy.	Anne O'Donnell	Rachael Cahir

WELLINGTON BLOOD AND CANCER CENTRE

CAST BM12: Study using cyclophosphamide after sibling-donor allogeneic stem-cell transplantation (CAST) in patients with acute leukaemia and myelodysplasia	Travis Perera	LJ Geniston
CLL 14: A prospective, open-label, multicenter, randomized phase III trial to compare the efficacy and safety of a combined regimen of Obinutuzumab and GDC0199 (ABT-199) versus Obinutuzumab and Chlorambucil in previously untreated patients with CLL and coexisting medical conditions.	Rob Weinkove	Debra Morriss
COSMIC XL 184-313: A randomised, Double Blind, Controlled Phase 3 study 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	Jonathan Graham	Rachael Cahir
DREAMM7: Study to Evaluate the Efficacy and Safety of the Combination of Belantamab Mafodotin, Bortezomib, and Dexamethasone (B-Vd) Compared with the Combination of Daratumumab, Bortezomib and Dexamethasone (D-Vd) in Participants with Relapsed/Refractory Multiple Myeloma.	Anup George	Charisse Gleeson
ENABLE-2 Car T-Cell: Enhancing Chimeric Antigen Receptor T-cell Therapy for Aggressive B-cell Lymphoma by Employing a TLR2 domain	Rob Weinkove	Tess Ostapowicz LJ Geniston
(EXPERT) - /ANZBCTG: EXamining PErsonalised Radiation Therapy for low-risk early breast cancer	Anna Nicholson	Debra Morriss Mariska Van Essen
FINER: A double-blind placebo controlled randomized phase III trial of Fulvestrant and Ipatasertib as treatment for advance/metastatic HER-2 negative and estrogen receptor positive (ER+) breast cancer following progression on first line CDK 4/6 inhibitor and aromatase inhibitor	Sarah Barton	Ana Enriquez Mariska van Essen
Genetics of Myeloma: Genetics of Myeloma and related diseases	Huib Buyck	Olivia Whitford
HOVON: A phase 3, multicenter, double-blind, randomized, placebo-controlled study of ivosidenib or enasidenib in combination with induction therapy and consolidation therapy followed by maintenance therapy in patients with newly diagnosed acute myeloid leukemia or myelodysplastic syndrome with excess blasts-2, with an IDH1 or IDH2 mutation, respectively, eligible for intensive chemotherapy	Travis Perera	Francois Lategan LJ Geniston
IKEMA: Phase 3, Randomized, open label, multicenter study assessing the clinical benefit of isatuximab combined with carfilzomib (Kypriolis®) and dexamethasone versus carfilzomib with dexamethasone in patients with relapsed and/or refractory multiple myeloma previously treated with 1 to 3 prior lines	Anup George	Francois Lategan Charisse Gleeson
INTERVENE AML25: An ALLG Phase 2 study to Investigate Novel Triplets to Extend Remission with VENetoclax in Elderly (INTERVENE) Acute Myeloid Leukaemia	Travis Perera	Lj Geniston Francois Lategan
KEYNOTE-412: A Randomized Phase III study of pembrolizumab given concomitantly with chemoradiation and as maintenance therapy versus chemoradiation alone in subjects with locally advanced head and neck squamous cell carcinoma	Jonathan Graham	Ana Enriquez
KISS: Kinase Inhibition with Sprycel Start-Up. A phase II study of dasatinib followed by imatinib in newly diagnosed, previously untreated patients with chronic phase CML	Alwyn D'Souza	Charisse Gleeson
Magnetismm 5: Phase 3 Study of Elranatamab (PF-06863135) Monotherapy and Elranatamab + Daratumumab Versus Daratumumab + Pomalidomide + Dexamethasone in Participants With Relapsed/Refractory Multiple Myeloma	Anup George	Olivia Whitford Charisse Gleeson
M19 388 (VENICE II rollover): Evaluating the Impact of Venetoclax on the Quality of Life of Relapsed/Refractory Subjects with Chronic Lymphocytic Leukemia (CLL) Including those with the 17p Deletion or TP53 Mutation OR Those Who Have Received Prior Treatment with a B-Cell Receptor Inhibitor.	Rob Weinkove	Debra Morriss
MK339-006: A Ph3 Study of Pembrolizumab in Combination with Pemetrexed/Platinum (Carboplatin or Cisplatin) Followed by Pembrolizumab and Maintenance Olaparib vs Maintenance Pemetrexed in the First-Line Treatment of Participants with Metastatic Nonsquamous on-Small-Cell Lung Cancer.	Brendan Luey	Francois Lategan Rachael Cahir
MK339-008 : A Phase 3 Study of Pembrolizumab in Combination with Carboplatin/Taxane (Paclitaxel or Nab-paclitaxel) Followed by Pembrolizumab with or without Maintenance Olaparib in the First-line Treatment of Metastatic Squamous Non-small Cell Lung Cancer	Brendan Luey	Ana Enriquez Rachael Cahir
MK3475-054/EORTC: Adjuvant immunotherapy with anti-PD-1 monoclonal antibody MK-3475 versus placebo after complete resection of high-risk Stage III melanoma: A randomized, double-blind Phase 3 trial of the EORTC Melanoma Group.	Catherine Barrow	Rachael Cahir
MK3475-587: 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.	Catherine Barrow	Ana Enriquez
MRDR Registry: Myeloma & Related Diseases Registry	Anup George	Anup, Kelly Harrison & CTU
NBCR (ALLG): The Australasian Leukaemia & Lymphoma Group National Blood Cancer Registry and Biorepository	Travis Perera	LJ Geniston Rachael Cahir
Purple Registry: Pancreatic Cancer: Understanding Routine Practice and lifting end results (PURPLE). A prospective pancreatic cancer clinical registry	Kate Clarke	Tati Cocker
Roche BP43963 PD1/LAG 3 : study of multiple doses of RO7247669 in participants with previously untreated unresectable or metastatic Melanoma	Catherine Barrow	Ana Enriquez
Roche CLL14: A Prospective, Open-Label, Multicenter, Randomized Phase III Trial To Compare The Efficacy And Safety Of A Combined Regimen Of Obinutuzumab And GDC-0199 (ABT-199) Versus Obinutuzumab And Chlorambucil In Previously Untreated Patients With CLL And Coexisting medical conditions	Rob Weinkove	Deb Morriss
SPAR: A randomised, placebo-controlled phase II trial of Simvastatin in addition to standard chemotherapy and radiation in preoperative treatment for rectal cancer	Anne O'Donnell	Jenn Dalen
TRILOGY : A Phase III, Double-Blinded, Randomized, Placebo Controlled Study Of Atezolizumab Plus Cobimetinib And Vemurafenib Versus Placebo Plus Cobimetinib And Vemurafenib In Previously Untreated Braf V600 Mutation Positive Patients With Unresectable Locally Advanced Or metastatic melanoma	Catherine Barrow	Ana Enriquez Rachael Cahir

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WELLINGTON BLOOD AND CANCER CENTRE CONTINUATION

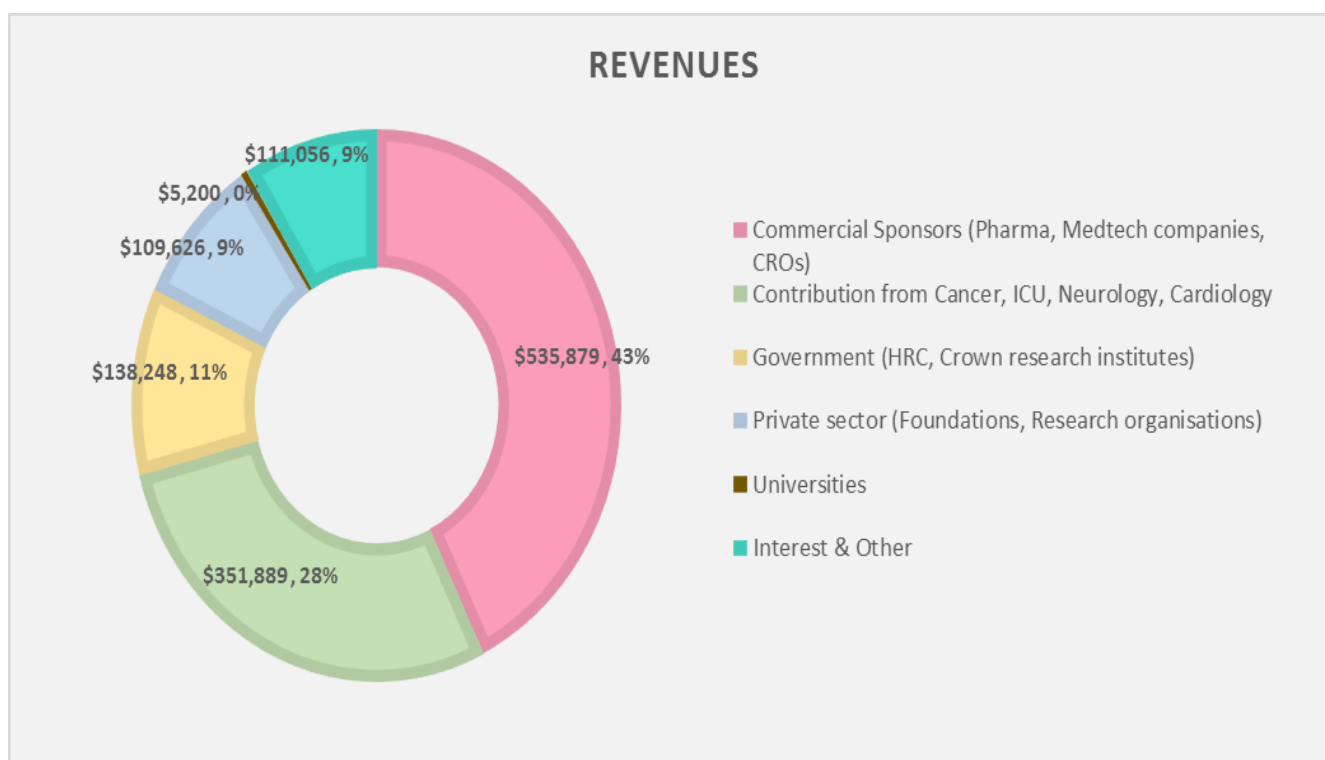
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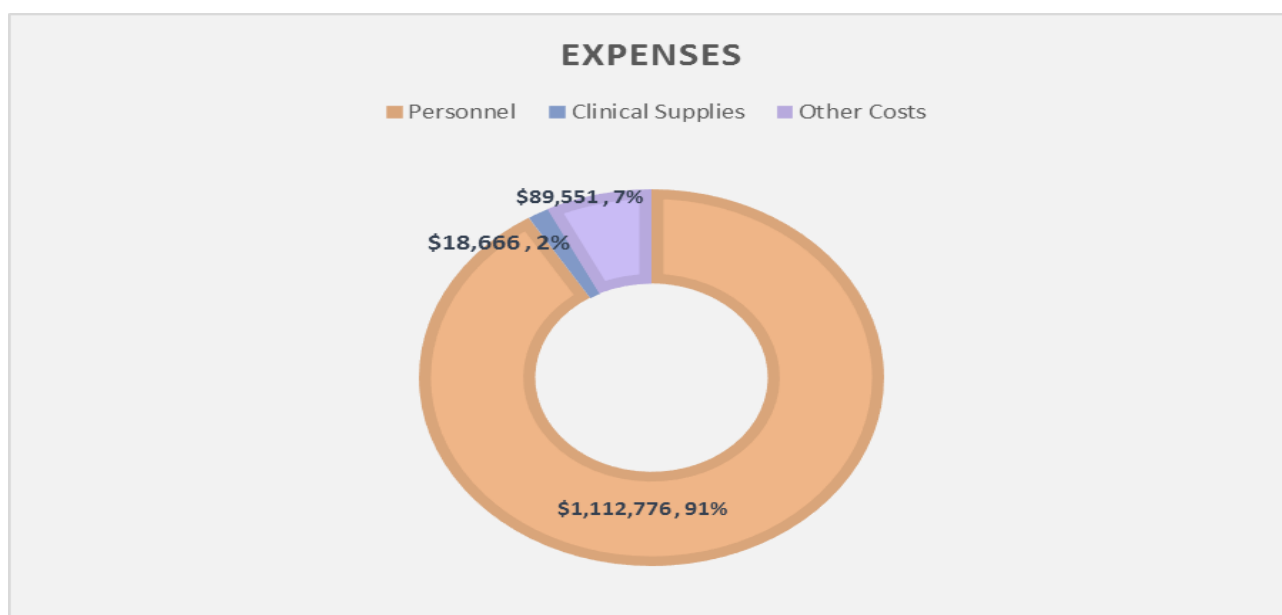
Research Office and Clinical Trials Unit Financial Report

Revenues	July 2022 – June 2023
Commercial Sponsors (Pharma, Medtech companies, CROs)	\$535,879
Contribution from Cancer, ICU, Neurology, Cardiology	\$351,889
Government (HRC, Crown research institutes)	\$138,248
Private sector (Foundations, Research organisations)	\$109,626
Universities	\$5,200
Interest & Other	\$111,056



Research Office and Clinical Trials Unit Financial Report

Expenses	July 2022 – June 2023
Personnel	\$1,112,776
Clinical Supplies	\$18,666
Other Costs	\$89,551



	30 June 2021	30 June 2022	30 June 2023
3 year Research Office account balance	\$2,380,308	\$2,454,821	\$2,534,852

