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About us

Aotearoa Clinical Trials (ACTT), formerly Middlemore Clinical Trials, has been a pivotal force in New Zealand's clinical research for over 20 years.

ACTT operates fully integrated research units at both Middlemore Hospital in South Auckland and Whangārei Hospital in Northland, covering over 32 therapeutic areas and running more than 150 clinical trials. These units are staffed by over 50 skilled professionals, including research nurses, trial coordinators, pharmacists, and regulatory specialists. Middlemore Hospital, New Zealand's largest and most advanced tertiary hospital, serves a population of over 600,000 people in the Counties Manukau region, while Whangārei Hospital, the largest healthcare facility in Northland, serves as a vital support hub for smaller hospitals in the region. This reflects our commitment to expanding clinical research across New Zealand.

As an independent charitable trust, ACTT manages both commercial and grant-funded research in close partnership with public hospitals. Uniquely, we oversee clinical trials across all hospital departments, giving us unparalleled experience in diverse therapeutic areas. Our centralised approach to trial management, including feasibility assessments, marketing, and accounting, provides a robust framework for complex trials.

In 2023, our rebranding to Aotearoa Clinical Trials marked our evolution into a national leader, committed to establishing research sites across New Zealand. In 2024, we achieved a significant milestone as the first site in the country to attain both Global Clinical Site Accreditation (GCSA) certification and Workforce Quality Accreditation. These prestigious certifications affirm our commitment to the highest standards of quality and excellence in clinical research, positioning us as a leader capable of delivering world-class trials.

ACTT's deep partnership with Middlemore Hospital has provided invaluable insights into the health challenges of New Zealand's diverse communities, particularly those disproportionately affected by acute and chronic conditions. This experience allows us to navigate the complexities of the health system and customise our clinical trial management model to meet the unique challenges of various sites across the country, while minimising financial, regulatory, and legal risks for our hospital partners.

Our exclusive focus on clinical trials means we understand the needs of sponsors, researchers, and participants. We are dedicated to engaging with our diverse local communities and expanding partnerships with sponsors in biopharmaceutical and medical device trials. As we continue to grow, we remain committed to advancing world-class clinical research throughout Aotearoa.





ACTT has become the first research organisation in New Zealand to achieve both GCSA certification and workforce quality accreditation.

Foreword from the Chair



Greg Batkin, Chair

The 2024 financial year reflected that the number of trial activations was the lowest in at least 6 years, a factor largely beyond the control of the CEO and his team.

Nonetheless the unit's growth trajectory appears to be largely intact, as the number of feasibility studies received in FY24 grew by almost 50% over the number received in FY23, reflecting sponsors real interest in working with Aotearoa Clinical Trials (ACTT).

This is at least in part due to the hard work of the team, and the reputation for speed of set up, lack of regulatory hurdles and the high quality of the data produced by ACTT.

The high number of feasibility studies received, a leading indication of future activity, points to a very busy FY25. Already the number of activations in Q1 FY25 exceeds the number for the first half of FY24.

The increasing surplus' that these trials will generate will further enhance the funds available for investment in research and other projects for the betterment of health outcomes of the Trust's patients.

It is also pleasing to see the progress towards other strategic goals, in particular the developing relationship with Whangārei Hospital, the enhancement of the unit's capacity to undertake phase Ib trials and the implementation of new IT systems. The new technologies being brought to our patients by the trials undertaken at ACTT is also very exciting.

All of this is happening against a backdrop of significant changes in the health sector in New Zealand, which creates further challenges in achieving strategic objectives, and of course increases the complexity of the environment in which the ACTT team work.

The board acknowledges the important contribution to ACTT made by Dr John Baker who stepped down from his Clinical Director role in March this year after almost 20 years. John joined CCRep in October 2005. He took on the Clinical and Executive Director role in 2013, following the resignation of the General Manager and managed the unit through a very difficult period. He stepped down from the CED role in 2018 to assume his current CD role.

The board thanks the team for their efforts and significant achievements (despite the difficulties outlined above) over the course of the year under review.

We also thank the important group of researchers and physicians at both Middlemore and Whangārei, whose expertise is critical to everything that ACTT does.

CEO's report

The past year has been a year full of challenges for the unit. We have navigated a fluctuating flow of new trial activations, significant changes to the New Zealand health system, and the partnership with and activation of additional hospital and satellite sites.

Throughout, we have grown both in terms of capability and capacity to deliver world class clinical trials to the communities we serve. This has involved a deeper understanding of staff competencies and strengths resulting in a framework in which we can create a culture of continuous learning and improvement.

Additionally, it was very pleasing to be the first research organisation in New Zealand to receive accreditation as a research site of clinical excellence from the UK-based International Accrediting Organisation for Clinical Research (IAOCR). This confirms our status as a site that has systems and processes which are world-class.

Such evolution is essential as we see New Zealand and our hospital based researchers well positioned and more attractive to biotech and pharmaceutical companies who are recognising the advantages of performing more early phase research in Australia and New Zealand. Our speed in setup and the quality of the data we can produce are being noticed and valued. This is evidenced by the record number of trial feasibilities we received over the last 12 months from a growing number of sponsors.

We have aimed to significantly enhance our Phase Ib capacity with the development of onsite pharmaceutical compounding and dedicated Phase Ib facilities. This would not have been possible without the help and support of Counties Manukau Health management and the drive and focus of Aotearoa Clinical Trials (ACTT) management.

There is excitement for our participants and research physicians to be involved in cutting edge technology in the areas of CRISPR, novel immunotherapy and metabolic agents that have the potential to significantly change both patients' lives and the medical landscape.

We have successfully completed our migration to a world class paperless clinical trial document management system for trial source documentation, and we are starting to reap the benefits in efficiency and quality. We are now looking towards the natural evolution of the involvement of AI in helping improve our process management in real time.

Research led

Our growth in collaborative group and investigator initiated grant trials has been very satisfying. By attracting talented staff and winning more contracts than ever before, we are able to offer a wider array of services to clinicians and researchers in Middlemore and Whangārei Hospitals. This allows hospital clinicians that we partner with to develop the academic aspect of their professional career. We assist them in forming international relationships, securing funding, devising budgets and project management strategies, navigating regulatory hurdles as well as helping them publish articles on their work. Few hospitals in the country can offer such a service to their clinicians interested in research.

Looking ahead we now have the resources to help invest and support other hospital based researchers throughout New Zealand so they too can offer novel clinical trials to their communities and perform high impact grant trials. This year we will be reaching out to some of them to offer support in an environment that continues to make involvement in medical research difficult.

None of this can occur in a vacuum. We cannot do what we do without the support of our innovative and experienced Board of Trustees, the hospitals we partner with, the international sponsors who trust us with their trials and importantly the talented research physicians and staff who perform the research.

I would also like to thank Dr John Baker's extraordinary contribution to the unit as he stepped down as Clinical Director of ACTT in March 2024 after many years of service. His expertise in clinical trials makes him a leader in the field. John has inspired and supported many clinical staff in their research journey.

The community is the lifeblood of any organisation. Our relationship with our local manawhenua continues to strengthen through the wise guidance and counsel of Matua Robert Clark. Additionally, our solid relationship with the Pacifica provider SouthSeas Health means that our understanding and ability to engage with Pacifica communities in research continues to grow.

Ngā manaakitanga (With best wishes) **Dr Edward Watson** CEO

Board of Trustees FY24



Greg Batkin

Greg brings to the board a range of commercial, financial and strategic skills. Greg has had experience in various business sectors, including automotive, energy, agriculture and life sciences. In addition to his role as Chairperson of ACTT, Greg is Deputy Chair of Safer Sleep (an anaesthetic software company), a director of a large private business based in South Auckland, and a Trustee of Cancer Research Trust New Zealand.



Dr Pete Watson

Pete is a medical graduate of Otago University and completed his specialist training as a Paediatrician. He began his career as a Consultant at Counties Manukau Health as a clinical academic at the University of Auckland in 1996. Pete worked at CMH until 2022, contributing to Child and Youth Health, Mental Health & Addictions. He has held various local, regional and national clinical leadership roles, most recently he has been the Chief Medical Officer, Deputy CEO and then Acting CEO at Counties Manukau DHB. Following the formation of Te Whatu Ora, Pete moved into the Interim Te Whatu Ora National Medical Director role until June 2023.



Sanjoy Nand

Sanjoy is currently the Chief of Allied Health Scientific and Technical at Te Whatu Ora, Counties Manukau. He is an experienced health sector leader with a background in clinical and operational leadership roles within the New Zealand public healthcare system. Originally trained as a pharmacist, Sanjoy also has extensive knowledge and experience in the pharmaceutical sector. He is a Chartered Member of the Institute of Directors.



Kevin Wightman

Kevin graduated in Pharmacology from Nottingham University in the UK and has worked in Australia for over 20 years. He is passionate about improving the delivery of clinical trials to better meet patients' needs, with more than 25 years experience in leading Pharma, CRO, site, and patient centric solution providers across Asia Pacific, the US and Europe. Kevin brings unique perspectives, stakeholder networks and insights from both industry and site angles, drawing from his experience with industry associations and not-for-profit Board Director experience.



Whetumarama Parore

Ngāti Whātua, Ngāpuhi, Ngāti Kahu, Ngāti Poneke Marama has worked in the New Zealand health sector for over 30 years, holding roles in various organisations and NGOs. Her positions have included General Manager Māori Health and Access & Optimal Use for PHARMAC and Pou Ahorangi - CEO for Te Rau Matatini the National Māori Mental Health and Addiction workforce. She has also served as Whānau Voice Lead T Te Aka Whai Ora -Māori Health Authority. Marama currently works for Whaikaha - Ministry of Disabled People. She is a trustee of Te Houhanga Marae and Pipitea Marae in Wellington. Marama lives in Porirua with 18 mokopuna, who also whakapapa to Ngāti Toa.



Michael James

Michael's international career has spanned commercial and financial leadership roles across hi-tech and innovation industries in both public and private sectors. He is an experienced director in the infrastructure and innovation sector and brings a wealth of commercial and strategic thinking expertise to the Board.

Senior management



Dr Edward WatsonChief Executive Officer



Dr John Baker Clinical Director



Karen Carter Research Operations Manager

Karen's team

The Operations Team is a multi-disciplinary team that encompasses nursing, coordination, phlebotomy, laboratory and pharmacy. Collectively, we play a crucial role in ensuring the smooth and efficient execution of clinical trials. We are responsible for all logistical aspects of the study, from managing time lines and budgets to ensuring regulatory compliance and quality control. Additionally, we provide clinical care and support to trial participants and their whaanau.

We work alongside ACTT's internal teams and other stakeholders, including investigators, sponsors, and regulatory bodies, to ensure that every trial is meticulously planned and executed. The Operations Team ensures that studies are conducted according to protocol, on time, and within budget, ultimately contributing to the generation of reliable and accurate data that can lead to new medical treatments and advancements in healthcare.

During FY2024, the Operations Team underwent a restructure. The new structure enables individuals with a BSc, MSc or PhD in Biomedical Science, but no clinical research experience, to gain hands on experience in clinical trial management. It's comparable to a paid internship, where people are paid to learn on the job. This approach provides an opportunity for people to enter the field without prior experience and to progress to Clinical Trial Coordinator or management level in a supported manner. So far, three of our team have progressed from Clinical Trial Assistant to Research Associate, and one from Clinical Trial Assistant to Clinical Trial Coordinator.



Emani Setefano Finance Manager

Emani's team

The ACTT Finance team consists of financial experts who excel in managing the intricacies of cash flow and budgeting. They ensure that the organisation remains financially stable, supporting smooth operations. The Finance team translates financial data into actionable strategies, ensuring timely payments and financial stability. Their diligent work behind the scenes allows the science to progress and ensures the Trust's financial health remains robust.



Kate Msiska Business Manager

Kate's team

My team comprises the behindthe-scenes experts for the Commercial portfolio, including a Regulatory Lead, a Marketing and Recruitment Specialist, Start-up Specialists, and a Start-up Associate. We manage everything from new business and feasibility coordination to contracts, budget negotiations, and regulatory processes, while also handling investigator and sponsor relationship management. Our Marketing and Recruitment Specialist is the storyteller, crafting content and enhancing our online presence to inform sponsors, funders, investigators, and potential participants about the amazing work we do.



Dr Nicola JacksonGrants Manager

Nicola's team

We're a team with a big mission: to support ground-breaking, grant-funded research that tackles real healthcare challenges. From investigator-initiated projects to collaborative studies, we're all about supporting innovative ideas and making them a reality.

We're here from start to finish for grant funded research - helping researchers write protocols, secure funding, setting up studies, managing projects, and everything in between. We turn concepts into concrete outcomes and make sure every dollar counts. By reinvesting revenue from our commercial trials into these essential studies, we not only advance scientific knowledge but also drive policy changes and expand treatment access across Aotearoa New Zealand.



Alan Smith (retired)
Information Systems Manager

Resident Investigators



L-R May Lim, Dr Aritra Ray, Dr Renate Koops, Dr Ian Rosen, Dr Joanna Wojciechowska

At ACTT we have access to general physicians, also known as Resident Investigators or Research Physicians, who themselves work within the hospitals we partner with. Often departments wish to take part in research, but don't have time or resources to do so and need additional support from experienced investigators. Our Resident Investigators are here to assist and help perform high quality clinical trial activities for all medical disciplines including collaboration with clinical trial coordinators and nurses.

Dr Ian Rosen

"My main motivation for involvement in clinical research is being at the forefront of new medications that are in development for diseases such as diabetes and lipid disorders."

Dr Aritra Ray

"I am passionate about clinical research because prevention is better than cure. I'm driven by the opportunities to help design strategies, like vaccines, to tackle both current and emerging health issues.

Dr Joanna Wojciechowska

"If I can help to save even one life – then everything makes sense."

Dr Renate Koops

"Clinical research is vital for advancing our knowledge about safety and effectiveness of new treatments, ultimately improving patient care. Without clinical research, there is no future in medicine."

Dr May Lim

"I am very excited to be part of groundbreaking medical advancements that improve patient outcomes and help shape the future of healthcare. I appreciate that clinical research allows me to maintain a strong element of patient contact when assessing trial participants, while also engaging in important non-patient-facing work."

The Staff Awards



L-R Courtney Armstrong, Anne Kendall, Research Operations Manager Karen Carter, Louise Stubbing

Courtney Armstrong CERTIFICATE OF EXCELLENCE

For consistently demonstrating excellence through their efforts and interactions with other staff.

Anne Kendall THE ACTT AWARD

For consistently demonstrating the Company Core Values through their thoughts and actions.

Louise Stubbing CERTIFICATE OF EXCELLENCE

For consistently demonstrating excellence through their efforts and interactions with other staff

"What motivates me to work in clinical research is the team spirit and the generosity of volunteers who give their time and health to further medical advancements."

Dr Aritra Ray, Resident Physician

What we do

As New Zealand's largest clinical trial provider, Aotearoa Clinical Trials (ACTT) is committed to improving health outcomes across the country. Through our diverse portfolio of commercial, grant-funded, collaborative, and investigator-initiated trials, we are advancing medical research and providing our communities with access to cutting-edge therapies.

Commercial trials

At ACTT commercial trials are at the heart of our work. These industry-sponsored trials, backed by international biopharmaceutical companies, range from Phase I to Phase IV, reflecting the complexity and scope of modern clinical research.

Grant-funded trials

Grant-funded trials are diverse in size, duration, and complexity, supported by external granting agencies such as the Health Research Council, as well as surpluses from our commercial trials or contributions from other research groups and providers. These trials play a crucial role in advancing medical knowledge and improving healthcare outcomes in New Zealand.

Grant funded trials comprise of either collaborative group or investigator-initiated trials.

Collaborative group trials

Collaborative group trials bring together research leaders from various fields to work collectively on ground-breaking studies. These trials can operate on a regional, national, or international scale, leveraging the strengths and expertise of each participant to achieve meaningful research outcomes.

Investigator-initiated trials

Investigator-initiated trials are typically smaller in scale, where the investigator not only conceives the research idea but also develops the protocol and secures the necessary funding. These trials are often grant-supported and allow for innovative, investigator-led exploration in specific areas of interest.



Why we do what we do



At Aotearoa Clinical Trials (ACTT), we are driven by a commitment to improving health equity in New Zealand. We believe that by removing barriers to healthcare access and building trust in world-class clinical research, we can make a meaningful difference in the lives of our communities.

New Zealand is a country of contrasts, where disparities in access to high-quality healthcare are increasingly evident. At ACTT, we bring value to our communities by enhancing access to clinical trials, which helps to address these inequities. By participating in these trials, individuals gain a deeper understanding of their health and, in turn, achieve better health outcomes. Through our work, we demonstrate the benefits of research, planting the seeds of confidence in medicines and clinical trials that will benefit not only today's patients but also future generations.

We achieve this by partnering with some of the world's largest and most innovative biopharmaceutical and medical device companies, bringing their cutting-edge therapies to New Zealand. Our collaborations with public hospitals across the country enable us to make a

lasting impact on the health of all New Zealanders, one community at a time. Our network allows leading health investigators to offer world class treatments to patients in their regions, a goal made possible through our effective partnerships across the New Zealand health sector.

New Zealand can become a preferred location for global sponsors to conduct clinical research. Clinical trials conducted here benefit from a competitive advantage in terms of speed – both in trial setup and in meeting recruitment targets. At ACTT, we offer a highly experienced research workforce, driven by a passion to improve the health outcomes of our communities through clinical trials. By increasing the number of clinical trials in New Zealand, we expand the opportunities for our communities to access novel treatment options.

How we benefit the community

Aotearoa Clinical Trials (ACTT), in partnership with Middlemore and Whangārei Hospitals, is dedicated to enhancing health outcomes in the Counties Manukau and Te Tai Tokerau (Northland) communities by increasing access to clinical trials. These trials provide direct benefits to participants, offering advanced treatments and personalised care that would otherwise be out of reach.

Personalised and patient-centred care

Through clinical trials, participants receive dedicated time with specialist nurses, coordinators, and doctors. This personalised approach allows patients to feel heard and understood, fostering stronger relationships with their healthcare providers. This in turn leads to better adherence to treatment plans and improved overall health outcomes.

Improved health outcomes

Patients involved in clinical trials often experience better outcomes compared to those receiving standard care. For example, research conducted at Middlemore Hospital showed that patients participating in overall mortality and an 80% decrease in cardiovascular-related deaths over three years.

Early access to cutting-edge treatments

Many ground breaking medications are not yet available through New Zealand's healthcare system due to PHARMAC purchasing policies or high costs. Clinical trials offer patients early access to these treatments often years before they become more widely available o the New Zealand public at no cost, allowing participants to benefit from innovative therapies that can significantly improve their quality of life.

Addressing health inequity

ACTT's work is especially impactful for communities that have historically faced barriers to healthcare, such as Pasifika, Māori, and Indian populations. By engaging with and providing earlier access to care and novel treatments, clinical trials help to reduce health inequities and offer solutions to the unique challenges faced by these groups.

Supporting economic and social wellbeing

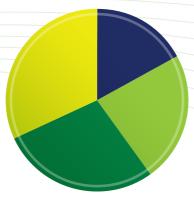
In the past year alone, ACTT contributed over \$375,000 in reimbursements to trial participants, helping to alleviate the financial burden of transportation, time away from work, and other costs associated with attending hospital appointments. This support ensures that patients can focus on their health without the added stress of financial barriers.

Community engagement and awareness

ACTT is committed to connecting with the communities we serve. We engage directly with local residents to raise awareness about the benefits of clinical trials and the access they provide to cutting-edge treatments. These events help build trust and educate the public about the importance of clinical research in improving health outcomes.

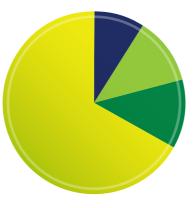
Our community

Ethnicity of CMDHB



- European & other 32%
- Māori 17%
- Pacific Peoples 23%
- Asian 28%

Ethnicity mix of trial participants at ACTT FY24



- European & other 67%
- Māori 9%
- Pacific Peoples 12%
- Asian 12%

Trust outcomes

Aotearoa Clinical Trials (ACTT) operates as a Charitable Trust, and our charitable status mandates a continuous commitment to investing in research initiatives and enhancing capabilities within Counties Manukau Health. Trust funds are maintained in the form of either general reserves or departmental funds.

The predominant allocation of the fund designated reserves in the fiscal year were directed toward enhancing research capabilities across different hospital departments. This encompassed various expenses, including the support of research personnel like Fellows and Nurses. Additionally, the Trust extended its assistance to hospital staff attending medical conferences with potential benefits for both the departments and patients.

General reserves

Total general reserves were \$2,049,296 (\$1,566,241 30 June 2023).

Departmental breakdown of granting from designated / restricted reserves

Туре	Designated Reserve
Research Fellow	558,779
Research Nurse	164,957
Conferences	84,630
Publication	22,860
Sponsorship	6,500
Misc	34,501

General performance dashboard EY24

STAFF



ALL STAFF

66

Total staff including contractors who worked at ACTT during FY24

RESEARCH STAFF

46

Includes Nurses, Clinical Trial Coordinators, Phlebotomist and Pharmacists

TRIAL METRICS



COMMERCIAL TRIALS

69

Total number of commercial trials underway in FY24

NEW TRIAL ACTIVATIONS

15

Commercial trials activated during FY24

GRANT FUNDED TRIALS

64

Total number of grant funded/ investigator led trials

COMMERCIAL FEASIBILITIES

243

Total feasibilities received during FY24

PARTICIPANT METRICS



NEW TRIAL PARTICIPANTS

164

TOTAL PARTICIPANTS

533

Includes ongoing multi-year trials

REVENUE



TOTAL REVENUE

\$11.6m

RESERVES SPENT

13%

Designated / restricted revenues spent on research activities during the year

RESERVES

\$6.9m

GRANT REVENUES

\$870k

Designated / restricted revenues spent during the year

Clinical performance dashboard FY24

HOSPITAL ACTIVITY
(Departments and



investigators)

ACTIVE DEPARTMENTS

32

Number of hospital departments we worked with in FY24

Middlemore 25 | Whangārei 7

ACTIVE INVESTIGATORS

63

Number of principal investigators involved in commercial trials in FY24

27 Principal Investigators

COMMUNITY CONTRIBUTIONS



REIMBURSEMENTS

\$375k

Reimbursements to our community for taking part in Clinical Trials

OUTPATIENT ACTIVITY



OUTPATIENT VISITS

\$375k

Total outpatient visits during the course of trials

RESERVES SPENT

13%

Designated / restricted revenues spent on research activities during the year

MONEY SAVED

\$1.65m

Estimated money saved by service outpatient visits

GRANT REVENUES

\$870k

Designated / restricted revenues spent during the year

Aotearoa Clinical Trials | Annual Report 2024

2024 Highlights

Aotearoa Clinical Trials becomes the first research organisation in New Zealand to achieve both GCSA certification and workforce quality accreditation



IAOCR and WQA

ACTT is proud to be the first research organisation in Aotearoa New Zealand to receive two prestigious certifications: the International Accrediting Organisation for Clinical Research (IAOCR) GCSA global quality standard as a centre of excellence for clinical trials, and the Silver Workforce Quality Accreditation (WQA). These two certifications were awarded after a rigorous, evidence-based assessment of our business operational (GCSA) and workforce processes (WQA).

The GCSA assessment involved a thorough review of our business operational procedures, including in-depth discussions with staff to gain a comprehensive understanding of how ACTT functions in terms of trial delivery. The review focused on seven key impact areas that are essential for the safe, effective delivery of clinical trials and for ensuring a high quality experience for both patient and sponsor/CRO journeys.

In addition, ACTT underwent the WQA assessment, which followed a similarly robust process, but was specifically aimed at evaluating our workforce processes. This assessment examined frameworks we have in place to ensure a high-performing, engaged, committed and competent workforce – factors that are crucial for reducing risk and delivering high quality clinical research.

Commercial trials in Whangarei

Surgical Device Trial

The Surgical Device Trial in Whangārei has recently been completed. We successfully met our enrolment targets, and feedback from investigators emphasised that our behind-thescenes efforts ensured a seamless trial experience. This support allowed them to concentrate fully on the participants and the device, contributing to the trial's overall success.

Cardiology Trial

This longer-term trial involves interventional cardiologists, the Cath lab, and Clinical Nurse Specialists. We have begun to enrol participants,

with enrolment set to continue over the next 18 months. This trial enables the Cardiology Department to engage in research that benefits both the local community and the Cardiology team.

Medical Oncology Breast Cancer Trial

This trial is underway. The department is eager to conduct research that provides access to medications otherwise unavailable to the community in Te Tai Tokerau. This trial also offers the entire oncology department an opportunity to be involved, demonstrating that a smaller hospital outside a metropolitan area can successfully conduct impactful research.

Aotearoa Clinical Trials partners with South Seas Healthcare to enhance Pacific health outcomes



ACTT has formed a significant partnership with South Seas Healthcare, a leading Pacific primary care provider, to address health disparities within Pacific communities in New Zealand. This collaboration aims to improve access to clinical trials for Pacific populations, who are often underrepresented in medical research. By working together, ACTT and South Seas Healthcare strive to bring cutting-edge treatments and therapies to Pacific patients, ensuring they benefit from the latest advancements in medical science.

South Seas Healthcare, established in 1999, is the largest Pacific health provider in South Auckland. The organisation offers a broad range of services, including primary care, mental health, social services, and youth programs, all tailored to meet the unique needs of Pacific communities. Through this partnership, South Seas Healthcare will leverage its deep community connections and trust to engage patients in clinical trials, helping to build awareness and participation among Pacific people.

This collaboration represents a critical step toward reducing health inequities in New Zealand by increasing Pacific representation in clinical research. ACTT brings its extensive experience in managing clinical trials, ensuring that these studies are conducted with the highest standards of care and ethical oversight. Together, ACTT and South Seas Healthcare are committed to making a meaningful difference in the health outcomes of Pacific populations by providing them with access to innovative treatments that were previously out

The partnership also underscores the importance of culturally competent care and the need to work closely with community-based organisations to address the specific health needs of diverse populations. Through this alliance, ACTT and South Seas Healthcare aim to create lasting improvements in the health and well-being of Pacific communities across New Zealand.

RealTime

In our ongoing commitment to enhancing efficiency and quality, ACTT has successfully migrated to the US-based RealTime eClinical platform. While ACTT had utilised a Clinical Trial Management System (CTMS) for many years, the transition to RealTime offers significant potential to further streamline our processes, increase organisational transparency and elevate the overall quality of our operations.

With the interation of eDocs, eSource, eRegulatory and eISF into our daily workflows, we have fully embraced digital transformation. From now on all new trials will have electronic, not paper based files, bringing us into alignment with the provision of gold standard clinical trials. Additionally, this platform provides the added benefit of enabling sponsors and CROs to monitor remotely, enhancing collaboration and oversight.

Feasibilities

ACTT experienced a record number of feasibilities over the past year, driven by increased awareness of our capabilities through marketing channels, networking at conferences, sponsor relationships, and, most importantly, our consistent performance - hitting participant recruitment targets and delivering high quality data.



Advancing surgical and medical research at Whangārei Hospital

A conversation with Dr Chris Harmston, Director of Research



Reflecting on recent projects, Chris highlights the completion of a long-term collaboration with the surgical research group STRATA, as well as ongoing data collection for the POET study. Both of these initiatives are set to make a substantial impact, and the team is eager to see the results. Looking ahead, Chris is excited about welcoming two new master's research candidates in the upcoming year, including a Māori fellow who will work under the supervision of Maxina Ronald. These candidates will contribute to the growing body of work coming from the surgical research team.

Chris and his department are focused on empowering early-career researchers, leading collaborative efforts in surgical research, and tackling issues relevant to Aotearoa New Zealand and its local populations. The partnership with ACTT has been particularly valuable. Chris notes that the collaboration has significantly enhanced their research capabilities, introducing Northland patients to a broader array of industry-funded trials and advancing their efforts in surgical research.



In terms of research streams, the general surgery team is engaged in three primary areas:

- National Collaborative Projects Led through STRATA and in partnership with ACTT, these projects focus on bringing together research teams from across the country to address pressing healthcare needs.
- Master's Research Program This program is expanding rapidly, with two current master's students and another two set to begin next year, further enriching the department's research output.
- 3. Trainee-Led Projects A critical component of the department's work, where surgical trainees lead research projects, gaining hands-on experience and contributing to the body of knowledge in surgical care.

However, Chris acknowledges that maintaining the high quality of research across a growing number of projects is a challenge. Securing funding for large-scale studies and balancing the diverse interests of researchers are also ongoing hurdles. Yet, despite these challenges, the team remains optimistic about the future. They hope to continue expanding their research capabilities in general surgery and aim to deliver a randomised controlled trial, a significant milestone for the department.

The surgical research team at Whangārei Hospital is poised for continued success, driven by a passion for research, collaboration, and a commitment to improving healthcare outcomes for patients across Northland and beyond.

Participant stories

Participant survey highlights

Rate your overall satisfaction with ACTT?

EXCELLENT

Rate the friendliness of our staff to you and your whanau?

88%

EXCELLENT

Would you recommend being involved in clinical research to others?

92%

YES

How would you rate your overall experience in being involved in clinical trial?

77%

EXCELLENT

Rate the caring concern of our staff to you and helping you understand your condition?

81%

EXCELLENT

Main reasons for participating in a trial



Doctor's recommendation 73%

Learn more about their condition

50%



Patient name: Robert C

Why are clinical trials important to you and your whānau?

As a father, grandfather, and someone of Māori descent, I have seen my family suffer from multiple illnesses and long-term conditions, often exacerbated by the shortcomings of business-driven healthcare systems. My faith in these systems is limited—they seem more focused on finding cures than on prevention, which is what truly impacts my family and me.

Research is incredibly important as it provides pathways to addressing current health challenges. In Māoridom, research is akin to the role of a tohunga (expert or healer)—it represents foresight in the face of illness. As Māori, we all possess the taonga (treasure) of rangatiratanga (sovereignty and leadership); we have this foresight. I believe that my living data today is far more valuable to helping prevent disease than data collected after my death. You can't solve a problem by only knowing that I died in my 50s from diabetes. It could have been prevented if I had been tested earlier. I believe that if I give the system my blood today, it will help them develop interventions, because prevention is better than cure.

My focus is on how we can extend the life expectancy of my people. How can we ensure that my people and family lead healthier, more active lives. I don't think we were designed to be unwell or to suffer. Our purpose is to enjoy the world in good health - that's what it's all about.

How did you find out about the clinical trial?

My wife was the driving force behind our involvement. Even though I work in the sector as a Treaty Partner, it was my wife who wanted to make a difference for our grandparents. We saw others undergoing different interventions, and so we decided to join the research program.

What was your experience like being part of a clinical trial?

My experience was very positive—I was well cared for and learned a lot about myself, including various aspects of my health. The care I received during the trial was exceptional. I got to explore both my healthiness and unhealthiness; my heart was tested, and many other assessments were done. Now, I'm looking forward to the future, knowing I did everything I could. It gave me hope, health, and peace of mind.

During the trial, I felt like I was at the forefront - I felt empowered for my people. I was doing something challenging, but I did it alongside my wife. One of



us received the real drug, and the other got the placebo; it was pretty clear who received what. I witnessed the treatment work firsthand as I saw positive changes in my wife, even though nothing changed for me. I would have loved for both of us to receive the active treatment.

Despite this, I still see health benefits from the trial. I gained valuable knowledge about my body that you don't typically get from regular doctor visits. The care and monitoring I received were exceptional.

Would you recommend others to participate in a clinical trial?

I am a strong advocate for clinical trials and encourage all my family to participate. Many of my family members are involved in different trials, especially those focused on cancer.

Any comments you would like to make?

Participating in a trial means you could be receiving something groundbreaking—you could be part of the prevention and breaking the cycle. I urge everyone to make themselves available for trials. Even if it doesn't prevent your illness, you will be well cared for and treated with respect.

Patient name: Andre

How did you find out about the clinical trial?

I was invited by Haematology. There were clinical trials and they tried to get me on it.

What was your experience like being on a clinical trial?

It has been very good. It is almost like having a private doctor look after you, its magnificent.

Would you recommend others to be part of a clinical trial?

Absolutely! If it doesn't benefit me, it will benefit others in the long run.

Any comments you would like to make?

I am 100% satisfied and very happy to be on the trial. I have had no negative experiences while being on the trial.



"I don't know if
I'm altruistic, but I
feel like I'm doing
the same thing
by participating
in this trial. I have
no fear of doing it,
and I don't think
others should be
scared either."

Patient name: Robert M

How did you find out about the trial?

I can't remember who rang me up, but I think Dr Mayanna Lund at Manukau Health Park. She asked me if I wanted to join, and I said 'Yeah!'. I've been on the trial for at least nine months now. The time has gone by quickly. This is a trial for heart failure.

What was your experience like being on a clinical trial?

Having blood tests, ask some questions – I have no problems with that. I don't mind coming into the hospital because I live locally, and I get paid for coming here and spending a couple of hours every few months, so I find it easy. Plus, there's a designated parking spot for me because I'm on the trial, which makes it handy. I don't have an issue coming here, but I do hope I get told the results, whether it makes any difference to me. One group gets the Real McCoy, and the other is just chalk. I'd like to know which one I'm on.

I was on a clinical trial for vitamin D by Auckland University about ten years ago. They wanted to see if taking vitamin D was beneficial, but I never heard the final results. My doctor asked if I had wanted to get on these trials. They need 'victims' but I don't see myself as a victim. We've moved past the witch doctor performing mumbo jumbo. I find that the benefits of being on a clinical trial helps the 'next poor bugger' who has this condition. They may get medication that prevents them from needing a bypass.

Would you recommend others to be part of a clinical trial?

Yes, I would recommend others to take part in a clinical trial. I currently volunteer as a coach for people in the Special Olympics – people with intellectual disabilities. I don't know if I'm altruistic, but I feel like I'm doing the same thing by participating in this trial. I have no fear of doing it, and I don't think others should be scared either.

Any comments you would like to make?

The staff are very knowledgeable and friendly. My questions are answered.

Patient name: Taylor

How did you find out about the clinical trial?

Through a family friend, who is also a researcher for Eosinophilic Esophagitis (EoE) in Alberta, Canada, told us, 'Hey, there's a trial for EoE coming to New Zealand, and I think you should try to get on it.' We contacted Taylor's specialist, who provided a referral, and our details were passed on to you, Emma, (Clinical Trial Coordinator). And here we are.

What was your experience like being on a clinical trial?

Good, yeah. It started with a Zoom call and then we came in for a clinic visit. The information provided made it easy to understand. Everything has been explained, and it's not too scary.

Taylor's Mum: "Everything has been explained to us very clearly, and everything has been pretty straightforward. Everyone has been really lovely, the team are really good."

Would you recommend others to be part of a clinical trial?

Yeah. It makes life easier and helps with the condition. It makes a big difference on a daily basis and makes eating more enjoyable. Taylor's condition makes it difficult to swallow food.

Being on the trial has given me the courage to try new foods and create recipes for new dishes.

Mum – "Taylor seems more relaxed. I don't think he realised how much his condition was affecting him. He seems more comfortable with eating and being involved in a clinical trial to see if it would make a difference to his condition and how he fits his life around it. The impact of EoE on us as parents wasn't clear at the time, but having access to this treatment has changed our lives as well as Taylor's. We don't have to be as mindful about eating or preparing certain foods."

Any comments you would like to make?

Being on this clinical trial and having access to this treatment has changed my energy. I'm feeling more positive about myself because I'm able to put on more weight, and it's exciting to see I am growing. The treatment on this trial has made life more enjoyable. If I didn't want to do something on this trial, I feel comfortable saying so.



"Everything has been explained to us very clearly, and everything has been pretty straightforward. Everyone has been really lovely, the team are really good."



Grant-funded trials and highlights

Aotearoa Clinical Trials (ACTT) has developed significant expertise in the managing of grant funded research. This includes both investigator-initiated and collaborative group studies that typically contribute to public good and provide insight into unmet patient and physician needs. This research has the potential to foster new international collaborations, drive policy change, and enable access to treatments that would otherwise be unavailable to patients in Aotearoa New Zealand.

Involvement in such research also allows researchers to develop the academic side of their career including involvement with academic centres around the world, journal article publication and recognition as leaders in their respective fields.

Many departments are involved in both commercial and grant funded research, leveraging the revenue generated from commercial research to support investigator-initiated and collaborative group studies. This 'virtuous cycle' is a strength of the ACTT model, as research funds are specifically ringfenced to support future research activity within the departments.

ACTT has a dedicated Grants team that supports clinical researchers at Middlemore and Whangārei

Hospitals in undertaking collaborative group and investigator initiated grant funded research. This support includes securing trial funding, refining protocols, creating budgets, obtaining regulatory approval, managing trials and data, recruiting patients, and providing medical writing services. Such services are essential in allowing busy clinicians in public hospitals to continue their academic pursuits and contribute to a culture of research excellence.

In FY24, the Grants team grew to include: two PhDqualified Grant Portfolio Managers (Drs Sumudu Ranasinghe and Alexandra Mowday), a Clinical Research Coordinator (Kate Wong She), a Research Associate (Georgia Fowler), and was led by Grants Manager (Dr Nicola Jackson).

During FY24, the Grants team supported 64 grant-funded clinical trials and research projects. Nineteen new studies were activated across the disciplines, including Respiratory, Paediatrics, Emergency Care, Surgery, ICU, Infectious Disease, and Mental Health. Investigators at Middlemore and Whangārei Hospitals conceived six of these studies. The Grants team also supported our investigators to secure over 2.5 million research funding, making FY24 our most successful year to date.



ACTT Grants Team

The Grants Team at ACTT welcomes and encourages research collaborations from around the world to support answering both local and international research questions that help our communities to thrive and drive novel science. Our innovative approach means we can often help with the finding of trial funding and support busy hospital clinicians to have both a fulfilling clinical and research driven career.

ROADMAP: 2024 Health Research Council Project Grant awarded

The Randomised Arthroplasty Infection Worldwide Multidomain Adaptive Platform Trial led by Dr Tom Hills and Dr Chris Luey (Infectious Diseases) at Middlemore Hospital, has been awarded a 2024 Health Research Council Project Grant. This study aims to identify the best management strategies for prosthetic joint infections (PJI).

The ROADMAP clinical trial seeks to identify the optimal surgical and antibiotic approaches to improve outcomes for people who experience a PJI, a condition that can significantly impact quality of life and if often challenging to treat. ROADMAP is an international trial coordinated by the University of Melbourne, Australia. ACTT will oversee the coordination of the New Zealand arm of the study.

Reducing Cardiac Risk in Outpatients with Serious Mental Illness study

The study, co-led by Dr Esra Soydinc (Mental Health) and Dr Mayanna Lund (Cardiology) at Middlemore Hospital, has been awarded funding by the Freemasons Foundation. This collaborative project between the Cardiology and Mental Health services aims to enhance the quality of life for patients with serious mental illnesses by improving access to cardiovascular risk monitoring and early intervention or referral to Cardiology.

The project focusses on facilitating access for people in South Auckland to receive cardiovascular disease (CVD) risk assessments and ECG tests, while also addressing challenges related to cost, staffing, and result interpretation. Grant Portfolio Manager, Sumudu Ranasinghe coordinated the protocol development and submission, working in collaboration with Pam Tregonning (Philanthropy) to secure the funding.



SNAP and PRO-SNAP Studies: The SNAP – Staphylococcus aureus Network Adaptive Platform trial

The SNAP trial aims to improve treatment outcomes for patients with Staphylococcus aureus bloodstream infections. The study currently includes sites in Australia, New Zealand, Singapore, Canada, Israel, South Africa, Europe and the UK.

New Zealand sites have made a significant contribution, with 417 platform enrolments (16% of global enrolments) and 542 registry enrolments (18% of global enrolments). New Zealand ranks third behind Australia and Canada.

PRO-SNAP Study

The "Promoting Equitable Access to Effective Treatment for Staphylococcus aureus Bacteraemia (SAB) in Aotearoa: Probenecid-Boosted Oral Antibiotic Dosing in the SNAP Study (PR-O-SNAP)," led by Dr Max Bloomfield (Wellington Hospital) and Dr Genevieve Walls (Middlemore Hospital, Infectious Diseases) has been awarded funding by the Te Niwha Infectious Disease Research Platform.

The aim of the study is to produce robust pharmacological and clinical data demonstrating that probenecid-beta-lactam combination therapy (PCT) achieves drug exposure that is equivalent to what is achieved with IV therapy. This would provide good evidence that prolonged IV antibiotic courses for SAB treatment can be safely shortened and replaced with oral treatment.

The Delirium Registry (DEL-REG 2023)

Titled "Creating a Surveillance System for Detection, Management, and Follow-Up of Delirium at Middlemore Hospital," the study is led by Dr John Hopkins (Liaison Psychiatry, Middlemore Hospital). The study has been awarded funding by the Ernest Hyam Davis and Ted and Mollie Carr Legacies (Perpetual Guardian).

New departments involved in grant research 2024 - Middlemore Hospital

- Anaesthetics SNaPP study started, with new feasibilities under assessment
- Mental Health Grant Portfolio Manager Sumudu Ranasinghe continues to work closely with Dr Ian Soosay and the Mental Health research team to develop and initiate new trials
- Stroke
- The National Burns Centre



Growth in Whangārei Hospital based research

We have two studies running as part of the STRATA network developed by Mr Chris Harmston - general surgeon and Research Director Whangārei (ACCORD and POET). Both are surgical audits that will be used to inform randomised controlled trials in the future. The data for ACCORD is being analysed, The Post-Endoscopy Tumour Study (POET) led by Dr Chris Harmston and Dr William Xu (Whangārei Hospital) (Surgery) has been awarded a Health Research Council 2023 Health Delivery Research Activation Grant and is managed by an ACTT project manager: Kate Wong She. This audit will define the rate and characteristics of post colonoscopy colorectal cancer (PCCRC) and post endoscopy upper gastrointestinal cancer (PEUGIC) across public hospitals in New Zealand. The overall aim of this research is to reduce the number of bowel and upper gastrointestinal cancers that are missed during an endoscopy test in New Zealand and to increase the number of cancers that can be prevented at the time of endoscopy. POET will be setup and run similarly to the Whangarei ACCORD study with trial Management support provided by the ACTT Grants team.

Over the last quarter we have set up and activated our first grant study in the Emergency Department at Whangārei Hospital: CRANIAC (Concussion Recovery Assessment of New Zealanders in Adolescence and Childhood). As CRANIAC was already running at our Middlemore Hospital trial site the ease of setting up the additional site at Whangārei emphasises the benefit of ACTT managing research at multiple hospital sites.

Two new Grant studies should be activated at Whangārei Hospital over the next quarter. These are the IMPEDE-PKD study (Implementation of Metformin therapy to Ease Decline of kidney function in Polycystic Kidney Disease Randomised Placebo-Controlled Trial) led by Dr Adam Mullins (Renal) and the TREAT-SC study (A Randomised, Double-Blinded, Placebo-Controlled Trial of Early, Short Course Oral Dexamethasone for the Treatment of Sydenham's Chorea in Children) led by Dr Ailsa Tuck (Paediatrics). Both of these studies are also being setup at Middlemore Hospital.

Grant funded trials by department FY24

Middlemore	
Cardiology	2
Diabetes	2
Emergency Care	9
Gastroenterology	1
Haematology	5
Infectious Diseases	4
Intensive Care	6
Mental Health	1
Neonatal	1
Ophthalmology	1
Paediatrics	21
Renal	2
Respiratory	5
Stroke	1
Total	61

Whangārei	
Emergency Care	1
Surgery	2
Total	3

Commercial trials

Aotearoa Clinical Trials (ACTT) is a dedicated Clinical Trial site management organisation specialising in clinical research. With a network of public hospitals and highly trained research staff, we are committed solely to research, and our focus on producing high-quality data ensures that the investments our sponsors make are rewarded. Our excellence as a clinical trial organisation is recognised in our recent accreditation by IAOCR (International Accreditation Organisation for Clinical Research).

Speed is crucial in clinical trials, and we excel in accelerating the process – from swiftly returning trial feasibilities and negotiating on contracts, assisting with obtaining Ethics approvals and importantly the rapid recruitment of participants. This ensures that studies are activated on time, maintaining the momentum that is vital in clinical research.

We take pride in our ability to recruit participants quickly, consistently achieving our target recruitment for the majority of trials. We also foster strong relationships with our participants, ensuring they adhere to and complete the trials they're involved in. This enduring connection is reflected in their enthusiasm to participate in future studies. Our commitment to CROs and sponsors is unwavering; we deliver the results we promise on every trial.



Our strengths

- International accreditation as a clinical trial organisation of excellence
- · Partnerships with leading clinicians: Collaborations across 25 hospital departments, ensuring diverse and expert oversight.
- Experienced research staff: Our team is highly trained and operates within ICH GCP guidelines and our unit's standard operating procedures.
- Rapid trial setup:
 - Quick feasibility assessments
 - Smooth navigation through Institutional Review Board (IRB) and Independent Ethics Committee (IEC) processes
 - Start-up specialists who ensure timely agreement on budgets and contract negotiations
- Tailored recruitment plans: Our recruitment team develops customised strategies for each trial to ensure we meet or exceed our recruitment targets.
- Access to diverse participants: We leverage our strong partnerships with Counties Manukau and Te Tai Tokerau communities, and local Primary Care Organisations, along with sophisticated social media and advertising channels, to reach motivated participants.
- Dedicated pharmacy and laboratory support: Our specialised teams ensure there are no delays in IP preparation and sample processing.
- Leading edge Clinical Trial Management (CTMS) and feasibility management systems.
- High-quality data generation: We provide global partners with:
 - Paperless regulatory and participant files
 - 24/7 remote monitoring access

We are driven by a mission to improve health outcomes and reduce health inequities within our communities through world-class clinical trials.

Commercial trials - feasibilities

Engagement by sponsors during FY24

Sponsor Pharmacyclics LLC Horizon Therapeutics AbbVie Theinova Valneva Imago Biosciences Vitality Health Foundation Insmed Boehringer Ingelheim Bausch Health LG Chem Ltd Janssen-Cilag Pty Ltd Aroa Biosurgery Pfizer BeiGene Loxo Oncology Roche Biotest AG Genentech Fisher & Paykel Healthcare Aatru Medical, LLC Beam MSD Novavax

VIR Biotechnology Sanofi **Chinook Therapeutics** Arrowhead Virion Therapeutics **CRISPR Therapeutics** AstraZeneca **United Therapeutics Eidos Therapeutics** Eupraxia Arrowhead Pharmaceuticals Sagimet Solarea Bio VitaSong

Elixir Medical Corporation Virion GlaxoSmithKline (GSK) Enanta Versanis Bio Avalyn

Keros Therapeutics

CRO

PPD	Medpace
PharmaSols	Southern Star Research
BioValeo	PAREXEL International
IQVIA	Syneos Health
PRA	Parexel
NAMSA	Mobius Medical
Novotech	Clarivate
ICON	Syneos

New feasibilities for clinical trials received

> FY24 243

> > 179

FY23

New trial feasibilities received in FY24: Middlemore Hospital

	I	1	I/II	II	II/III	III	Obs	TBA	Total
Anaesthesia						1			1
Cardiology	1			4		9		2	16
Clinical Lipidology	3		3	1		2			9
Dermatology	3		1	7	1	3		2	17
Diabetes								1	1
Endocrinology	1		2	6	1	8			18
Gastroenterology	1	1	1	5		12		4	24
General Medicine	1			1				8	10
Haematology	7		1	1	1	13		9	32
Hepatology	1			3	2	5			11
Infectious Disease			1						1
Mental Health			1	4				3	8
Neurology	2		1	2				3	8
Oncology	3		1	1	1	5		4	15
Ophthalmology	1		1			1		1	4
Orthopaedics				1					1
Paediatrics			1	2		6	1	2	12
Pediatrics				1					1
Plastics		1		1					2
Renal				4		2		3	9
Respiratory			1	8		5		6	20
Rheumatology				4		5		2	11
Stroke					2				2
Vaccinology			1	2		5		2	10
Total	24	2	16	58	8	82	1	52	243

New trial feasibilities received in FY24: Whangārei Hospital

	I	II	III	TBA	Total
Anaesthesia			1		1
Cardiology		2	3		5
Endocrinology		1			1
Intensive Care			1		1
Oncology	1	1	3	2	7
Renal			2		2
Rheumatology			1		1
Vaccinology		1	2		3
Total	1	5	13	2	21



FY24 ACTT commercial trial overview

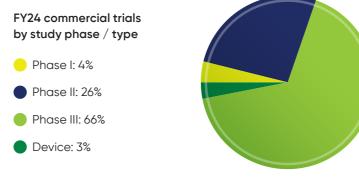
Active commercial trials

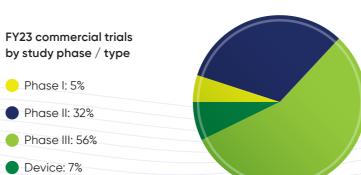
FY24	69
FY23	76

New trials activated

FY24 15

FY23 20





Trials by recruiting departments in FY24

<u> </u>		
Department	Trials	Participants
Cardiology	6	59
Clinical Lipidology	3	10
Dermatology	2	22
Diabetes	1	1
Endocrinology	1	30
Gastroenterology	5	18
General Medicine	1	26
Haematology	21	54
Hepatology	4	20
Neonatal	1	17
Orthopaedics	1	1
Plastics	1	6
Renal	1	5
Respiratory	5	18
Rheumatology	9	40
Stroke	1	6
Surgery	1	6
Vaccinology	5	213
Surgery	1	5
Vaccinology	5	216
Total	69	533

Areas of research – activity by department in FY24

Many of these trials provide patients with access to treatments that are otherwise not available in New Zealand or not available for the condition under investigation.

Cardiology Middlemore

The Cardiology Department covers all conditions related to heart disease. Dr Scott continues to lead a number of trials in his area of speciality, acute coronary syndrome. Dr Turaga is leading the Heart Failure trial which has completed enrolment, and Dr Borrie is leading the enrolling Atrial Fibrillation trial.

Dr Sutton's area of expertise is Cardiomyopathy, he leads a long-term study in this area providing patient access to treatments not currently funded in New Zealand. Dr Lund is supporting the continuation of the Multi-Ethnic New Zealand Study of Acute Coronary Syndromes (MENZACS) at Middlemore, with the assistance of nursing team members Renee McEwing and Chanthie Thach. Dr Looi continues to lead the long-standing Takotsubo Cardiomyopathy Registry at Middlemore Hospital.

Middlemore Clinical Lead:

Dr Mayanna Lund

CM Team

Dr Douglas Scott

Dr Andrew Borrie

Dr Mansi Turaga

Dr Tim Sutton

Dr Jen Li Looi Renee McEwing

Chanthie Thach

Cardiology Whangārei

Dr Chan is leading the first commercial trial in the Cardiology Department for some time. The Coronary Care and Cath Lab teams have been instrumental in supporting recruitment of acute patients following an acute coronary event

Whangārei Clinical Lead:

Dr Marcus Lee

Whangārei Team

Dr Daniel Chan

Dr Marcus Lee

Dermatology Middlemore

Research in the Dermatology Department focusses on conditions such as Alopecia Areata and Atopic Dermatitis. These trials provide patients with access to treatments that are otherwise not available in New Zealand, with some treatments being made available after trial completion if they show benefit.

Middlemore Clinical Lead

Dr Paul Jarrett

CM Team

Dr Cheng Huang Dr Leah Jones GRANT FUNDED TRIALS

2

COMMERCIAL TRIALS

5

COMMERCIAL TRIALS

1

COMMERCIAL TRIALS

2

Diabetes and Endocrinology

The ACTT Team led by Dr John Baker is conducting studies on the diagnosis and management of lipid disorders and cardiovascular safety in people with obesity. The pipeline is promising, with two Phase I CRISPR gene editing trials expected to start soon.

Middlemore Clinical Lead:

Dr Brandon Orr-Walker

Dr John Baker

GRANT FUNDED TRIALS

2

COMMERCIAL **TRIALS**

Emergency Department Middlemore

Research in the Emergency Department (ED) is led by Dr Eunicia Tan, Dr Chris Lash and Dr Andrew Brainard, with support from a team of dedicated Research Nurses. Current trials are non-commercial grant trials, either observational gathering data to guide or improve standard of care, or interventional studies comparing standard of care with an altered regimen or a different but known therapy.

GRANT FUNDED TRIALS

9

Middlemore Clinical Lead

Dr Matthew Clarke

CM Team

Dr Eunicia Tan Dr Andrew Brainard Dr Chris Lash Georgia Doyle Sandra Neva Helen Barrett Alex Grigg

Emergency Department Whangarei

The Whangarei ED has recently completed their first non-commercial grant trial with the University of Waikato investigating concussion recovery in adolescence and childhood.

Whangārei team:

Dr Stephanie Richling Lucy Benjamin-Mitchell **GRANT FUNDED TRIALS**

Gastroenterology and Hepatology Middlemore

Dr Tien Huey Lim is gaining international recognition and currently leading trials in Hepatology, Eosinophilic Esophagitis, Metabolic Dysfunction-Associated Steatohepatitis (MASH) and cirrhosis.

Dr Sriharan Selvartnam is leading two trials in Inflammatory Bowel Disease.

Middlemore Clinical Lead:

Dr Kumudith Ekanayaka

CM Team:

Dr Tien Huey Lim Dr Sriharan Selvartnam Dr Adele Melton Dr Emma Robinson Dr Mirthe Van der Valk

GRANT FUNDED TRIALS

COMMERCIAL **TRIALS**

9

General Medicine Middlemore

The ACTT team conducted a pilot study exploring the combined effects of medication and exercise for patients aged 60 and older, aiming to improve health outcomes and quality of life in this age group.

ACTT Clinical Director:

Dr John Baker

Haematology Middlemore

The Haematology Department continues to excel, conducting the most clinical trials and receiving the highest number of feasibilities. The Department's active portfolio includes commercial and grant funded research in conditions such as myelofibrosis, B-cell non-Hodgkin's lymphoma, chronic lymphocytic leukaemia/small lymphocytic lymphoma, multiple myeloma and more.

Middlemore Clinical Lead:

Dr Sharon Jackson

CM Team:

Dr Samar Issa

Dr James Liana

Dr Gordon Royle Dr Kirsty Marshall

Infectious Diseases Middlemore

Research led by Dr Susan Morpeth, Dr Genevieve Walls and Dr Chris Luey, with support from the ICU and Paediatric Research Nurse teams, and Pharmacy focuses on non-commercial collaborative grant trials investigating infectious diseases, including treatment strategies for Staphylococcus aureus bacteraemia, COVID-19, Legionnaires' disease, and Prosthetic Joint Infections.

Middlemore Clinical Lead:

Dr Chris Luev

CM Team:

Dr Susan Morpeth Dr Genevieve Walls Rima Song (ICU) Shirley Lawrence (Paediatrics)

Natasha Pool (Pharmacy)

Intensive Care Unit Middlemore

Led by Dr Tony Williams and supported by a team of research nurses led by Rima Song, the ICU focusses on trials investigating treatment strategies for community acquired pneumonia, the use of erythropoietin and dexmedetomidine in mechanically ventilated critically ill patients, as well as Sedation, Temperature and Pressure after Cardiac Arrest and Resuscitation.

Middlemore Clinical Research Lead:

Dr Tony Williams

CM Team

Dr Michael Borrie

TRIALS

COMMERCIAL

GRANT FUNDED TRIALS

5

COMMERCIAL **TRIALS**

21

GRANT FUNDED TRIALS

Rima Song

GRANT FUNDED TRIALS

6

COMMERCIAL **TRIALS**

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Medical Oncology Whangārei

Dr Edmond Ang is leading a study in advanced breast cancer - the first commercial trial to be led by Dr Ang and the team at the Cancer and Blood Service in Whangārei. The trial will provide treatment for patients who would not otherwise have access to any funded treatments.

COMMERCIAL TRIALS

1

Whangārei Clinical Lead:

Dr Vincent Newton

Whangārei Team

Dr Edmond Ang

Dr Miriam Duffy

Seji Joseph

Paediatrics and Neonatal Middlemore

The Paediatric and Neonatal Departments, led by clinicians from Kidz First Childrens Hospital, focuses on grant funded trials. With 23 active trials this year, the department concentrates on illnesses prevalent in the community, such as RSV, bronchiolitis, bronchiectasis, influenza, and acute rheumatic fever.

Middlemore Clinical Lead:

Dr Richard Matsas

CM Team:

Dr Adrian Trenholme

Dr Mike Meyer

Dr Rachel Webb

Dr Cass Byrnes

Dr Rebecca Alekzander Dr Adam Dennison

Shirley Lawrence

Gail Spence

Rachel Lee

Laarni Tundag

Maricar Maminta

Lisa Maravich

Plastics and General Surgery

Dr Michelle Locke and Dr Jenny Wagener (Middlemore) and Dr William Anderson and Dr Usha Shan (Whangārei) completed a first in human trial using a post-mastectomy surgical drain with the ENIVO Vacuum system with positive outcomes for both patients and their experience in trialling new technology.

CM Team:

Dr Michelle Locke

Dr Jenny Wagener

Whangarei team

Dr William Anderson

Dr Usha Shan

GRANT FUNDED TRIALS

22

COMMERCIAL TRIALS

1

COMMERCIAL TRIALS

2

Renal Middlemore

Renal Research continues to grow with a significant number of noncommercial grant trials in setup or under development in the areas of diabetic kidney disease and end-stage kidney disease.

Middlemore Clinical Lead:

Dr Joanna Dunlop

CM Team:

Dr Kalpa Javanatha

Dr Viliami Tutone

Dr Hari Talreja

Dr Jamie Kendrick-Jones

Renal Whangarei

The Whangarei Renal team, lead by Dr Adam Mullan, has recently setup their first non-commercial grant trial with ACTT in the area of Polycystic Kidney Disease.

Whangārei Clinical Lead:

Dr Adam Mullan

Respiratory Middlemore

The Respiratory Department is involved in a number of trials across different respiratory conditions including Bronchiectasis, COPD (Chronic Obstructive Pulmonary Disease), Idiopathic Pulmonary Fibrosis (IPF) and Progressive Fibrosing Interstitial Lung Disease (PF-ILD), Alpha-1 Antitrypsin Deficiency (AATD) and acute respiratory failure.

Middlemore Clinical Lead:

Dr Stuart Jones

CM Team:

Dr Conroy Wong

Dr Conor O'Dochartaigh

Dr William Good

Dr Jeffrey Garrett

Dr Elaine Yap

Rheumatology Middlemore

The Rheumatology Department actively collaborates on research initiatives with a focus on gout, systemic lupus erythematosus (SLE), Sjögren's syndrome, and rheumatoid arthritis.

Middlemore Clinical Lead:

Dr Mark Sapsford

CM Team:

Dr Sunil Kumar

GRANT FUNDED TRIALS

2

COMMERCIAL TRIALS

1

GRANT FUNDED TRIALS

1

GRANT FUNDED TRIALS

5

COMMERCIAL TRIALS

5

COMMERCIAL TRIALS

9

Stroke Middlemore

The Stroke Department is exploring new medications for acute patients, aiming to improve treatment outcomes and enhance recovery during the critical early stages of care.

Middlemore Clinical Lead:

Dr Arindam Kar

CM Team:

Dr Karim Mahawish Dr Ajay Kumar

TRIALS

GRANT FUNDED

COMMERCIAL TRIALS

1

Vaccinology Middlemore

The vaccine trials managed by the ACTT General Medicine physicians have maintained positive momentum, with ongoing recruitment for studies targeting vaccines against COVID-19, influenza, RSV, urinary tract infections, and staphylococcus aureus infections.



ACTT Clinical Director:

Dr John Baker



Reserve balances

Designated + Restricted Reserve	Opening balance	Granting	% Of opening	Closing balance
Cardiology Capex Fund	1,601,221	52,648	3%	1,589,481
Dermatology Research Fund	22,318	10,189	46%	31,840
Diabetes Fund	57,286	1,921	3%	55,616
Emergency Care Clinical Research & Education	44,676	861	2%	43,815
Gastro Research Fund (incls Hepatology)	430,787	29,500	7%	457,594
Haematology Research & Special Purposes Fund	1,198,917	96,107	8%	1,480,712
Home Health Fund	31,650	_		31,650
Intensive Care Unit Fund	525,353	99,613	19%	743,486
Infectious Diseases Research and Education Fund	144,477	931	1%	153,966
Kidz First Research Development fund	922,004	224,175	24%	825,934
Spinal Unit	24,428	_		24,428
Microbiology Fund	17,924	-		17,924
Neonatal Research	96,718	67,996	70%	111,071
Oropharyngeal Department Fund	8,742	-		8,742
Hand and Upper Limb Research Fund	148,534	31,180	21%	161,060
Radiology Research Fund	15,222	-		10,343
Renal Fund	78,112	29,714	38%	63,009
Respiratory Research Fund	578,765	111,341	19%	519,018
Rheumatology Research Fund	448,194	31,330	7%	503,828
Stroke Outcomes Fund	51,149	6,886	13%	47,689
Womens Health Fund	5,657	-		5,657
AT&R Research Fund	289	-		289
Anaesthetics & Surgical	5,000	107	2%	4,905
Orthopaedics	34,400	75,833	220%	42,178
Acute Allied Health	3,875	-		4,675
General Surgery	1,500	-		5,850
Ophthalmology	13,142	-		1
Plastics	3,000	-		14,860
Midwifery	1,300	-		1,300
Oncology	-	-	-	2,106
Mental Health	-	107		1,302
ARHOP	13,550	1,788		30,344
	6,528,191	872,227	13%	6,990,463

General Reserve

Closing balance	2,049,296
Opening balance	1,566,241

Revenue

	744,470
Other revenue	744.476
Non-commercial revenue [grants]	1,911,643
Commercial revenue	8,460,538

Publications FY24

Alexander, T., Asadi, S., Meyer, M., Harding, J. E., Jiang, Y., Alsweiler, J. M., ... Group, D. T. (2024). **Nutritional Support for Moderate-to-Late-Preterm Infants - A Randomized Trial**. *N Engl J Med*, *390*(16), 1493-1504. doi:10.1056/NEJMoa2313942

Anpalagan, K., Dotel, R., MacFadden, D. R., Smith, S., Voss, L., Petersiel, N., . . . Committee, S. T. G. T. S. (2024). Does adjunctive clindamycin have a role in Staphylococcus aureus bacteremia? A protocol for the adjunctive treatment domain of the S. aureus Network Adaptive Platform (SNAP) randomized controlled trial. Clin Infect Dis. doi:10.1093/cid/ciae289

Bandara, M. M., Barina, L. A., McPhee, G. M., Goulding, S. R., Denholm, J. T., Morpeth, S. C., . . . Group, A. (2024). Clinician perceptions of research priorities for the management of noncritically ill patients admitted to hospital with SARS-CoV-2 infection. *Intern Med J*, 54(2), 337–341. doi:10.1111/imj.16316

Bromberg, J. E. C., Issa, S., van der Holt, B., van der Meulen, M., Dirven, L., Minnema, M. C., . . . Doorduijn, J. K. (2024). Survival, neurocognitive function, and health-related quality of life outcomes after rituximabmethotrexate, BCNU, teniposide, and prednisolone for primary CNS lymphoma: Final results of the HOVON 105/ALLG NHL 24 study. *Neuro Oncol*, 26(4), 724–734. doi:10.1093/neuonc/noad224

Collaborative, S. (2023). Protocol for a national audit of the watch-andwait approach in patients with rectal cancer in Aotearoa New Zealand: The ACCORD study. *Colorectal Dis.* doi:10.1111/codi.16822

de Kretser, D., Mora, J., Bloomfield, M., Campbell, A., Cheng, M. P., Guy, S., . . . Staphylococcus aureus Network Adaptive Platform Study Group, m. (2023). Early oral antibiotic switch in Staphylococcus aureus bacteraemia: The Staphylococcus aureus Network Adaptive Platform (SNAP) Trial Early Oral Switch Protocol. Clin Infect Dis. doi:10.1093/cid/ciad666

Gane, E. J., Kim, W., Lim, T. H., Tangkijvanich, P., Yoon, J. H., Sievert, W., . . . Yuen, M. F. (2023). **First-in-human randomized study of RNAi therapeutic RG6346 for chronic hepatitis B virus infection**. *J Hepatol*, *79*(5), 1139–1149. doi:10.1016/j.jhep.2023.07.026

Gaudet, D., Clifton, P., Sullivan, D., Baker, J., Schwabe, C., Thackwray, S., . . . Ballantyne, C. M. (2023). **RNA Interference Therapy Targeting Apolipoprotein C-III in Hypertriglyceridemia**. *NEJM Evid*, *2*(12), EVIDoa2200325. doi:10.1056/EVIDoa2200325

Investigators, R.-C., Hills, T. E., Lorenzi, E., Berry, L. R., Shyamsundar, M., Al-Beidh, F., . . . McAuley, D. F. (2023). **Simvastatin in Critically III Patients with Covid-19**. *N Engl J Med, 389*(25), 2341-2354. doi:10.1056/NEJMoa2309995

Lau, E. P. M., Ing, M., Vekaria, S., Tan, A. L., Charlesworth, C., Fysh, E., . . . Lee, Y. C. G. (2024). Australasian Malignant PLeural Effusion (AMPLE)-4 trial: study protocol for a multi-centre randomised trial of topical antibiotics prophylaxis for infections of indwelling pleural catheters. *Trials*, 25(1), 249. doi:10.1186/s13063-024-08065-1

Lim, S. L., Wellard, C., Moore, E., Harrison, S. J., Hang, Q., Ho, J., . . . Spencer, A. (2023). Real-world outcomes in relapsed refractory multiple myeloma patients exposed to three or more prior treatments: an analysis from the ANZ myeloma and related diseases registry. *Intern Med J.* doi:10.1111/imj.16277

Long, E., Borland, M. L., George, S., Jani, S., Tan, E., Neutze, J., . . . New, Z. (2024). Sepsis epidemiology in Australian and New Zealand children (SENTINEL): protocol for a multicountry prospective observational study. *BMJ Open*, 14(1), e077471. doi:10.1136/bmjopen-2023-077471

Maria Patricia, H. M., Susan, M., Balasubramanian, V., Thomas, H., Joshua, D., Robert, M., . . . Jason, R. (2024). TMPRSS2 inhibitors for the treatment of COVID-19 in adults: a systematic review and meta-analysis of nafamostat and camostat mesylate randomised clinical trials. Clin Microbiol Infect. doi:10.1016/j.cmi.2024.01.029

Meyer, M. P., & Nevill, E. (2024). Early Breathing in Very Preterm Infants during Deferred Cord Clamping (DCC) Is Related to Gestational Age and Is Not Independently Associated with Important Neonatal Outcomes: A 5-Year Cohort Study. *Children (Basel)*, 11(3). doi:10.3390/children11030347

Morpeth, S. C., Venkatesh, B., Totterdell, J. A., McPhee, G. M., Mahar, R. K., Jones, M., . . . Tong, S. Y. C. (2023). **A Randomized Trial of Nafamostat for Covid-19**. *NEJM Evid*, *2*(11), EVIDoa2300132. doi:10.1056/EVIDoa2300132

Ninkovic, S., Harrison, S. J., Lee, J. J., Murphy, N., Lee, J. H., Estell, J., . . . Quach, H. (2024). Carfilzomib, thalidomide, and dexamethasone are safe and effective in relapsed and/or refractory multiple myeloma: final report of the single-arm, multicenter, phase II ALLG MM018/AMN002 study. *Haematologica*, 109(7), 2229-2238. doi:10.3324/haematol.2023.284238

Pabon, M., Cunningham, J., Claggett, B., Felker, G. M., McMurray, J. J. V., Metra, M., . . . Investigators, G.-H. (2023). **Sex Differences in Heart Failure With Reduced Ejection Fraction in the GALACTIC-HF Trial**. *JACC Heart Fail*, *11*(12), 1729-1738. doi:10.1016/j.jchf.2023.07.029

Pinter, J., Smyth, B., Stuard, S., Jardine, M., Wanner, C., Rossignol, P., . . . Genser, B. (2024). **Effect of Dialysate and Plasma Sodium on Mortality in a Global Historical Hemodialysis Cohort**. *J Am Soc Nephrol*, 35(2), 167-176. doi:10.1681/ASN.000000000000000262

Aotearoa Clinical Trials | Annual Report 2024

Rademaker, M., Jarrett, P., Murrell, D. F., Sinclair, R. D., Pasfield, L., Poppelwell, D., & Shumack, S. (2024). Cross-sectional burden-of-illness study in atopic dermatitis (MEASURE-AD) in Australia and New Zealand reveals impacts on well-being. Australas J Dermatol. doi:10.1111/ ajd.14308

Saito, S., Bennett, J., Nef, H. M., Webster, M., Namiki, A., Takahashi, A., . . . Collaborators, B.-R. (2023). First randomised controlled trial comparing the sirolimus-eluting bioadaptor with the zotarolimus-eluting drugeluting stent in patients with de novo coronary artery lesions: 12-month clinical and imaging data from the multi-centre, international, BIODAPTOR-RCT. EClinical Medicine, 65, 102304. doi:10.1016/j. eclinm.2023.102304

Tweedie-Cullen, R. Y., Jiang, Y., Brandon, R., Tay, A., Yeu, R., Smallman, K., ... Moffitt, A. (2024). Diabetes treatment satisfaction among a multiethnic Aotearoa New Zealand population with uncontrolled type 2 diabetes mellitus. N Z Med J, 137(1600), 66-75. doi:10.26635/6965.6341

Watts, G. F., Schwabe, C., Scott, R., Gladding, P. A., Sullivan, D., Baker, J., . . . Ballantyne, C. M. (2023). RNA interference targeting ANGPTL3 for triglyceride and cholesterol lowering: phase 1 basket trial cohorts. $\it Nat$ Med, 29(9), 2216-2223. doi:10.1038/s41591-023-02494-2

Wong, C., & Martinez-Garcia, M. A. (2023). Randomized Clinical Trials of Inhaled Antibiotics in Bronchiectasis: Cause for Optimism?. Chest, 163(1), 3-5. doi:https://doi.org/10.1016/j.chest.2022.09.003

Xu, W., McGuinness, M. J., Wells, C., Varghese, C., Elliott, B., Paterson, L., ... Collaborative, S. (2024). Protocol for a national, multicentre study of post-endoscopy colorectal and upper gastrointestinal cancers: The POET study. Colorectal Dis. doi:10.1111/codi.17057



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