Aotearoa Clinical Trials

Annual Report 2023

We're here to make a lasting difference to the health of our people

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Aotearoa Clinical Trials

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About us

Aotearoa Clinical Trials (ACTT) began its journey over 20 years ago.

A team of over 50 experienced highly skilled research staff remains based at Middlemore Hospital's fully integrated research unit in South Auckland – the largest in New Zealand.

ACTT is an independent charitable trust that manages both commercial and grant funded research in partnership with partnering public hospitals such as Middlemore Hospital in South Auckland and Whangarei Hospital in Northland (Te Tai Tokerau).

As distinct to the majority of other large hospitals we manage all clinical trials for all departments within the hospital. This gives us unrivalled experience in many different therapeutic areas. Additionally it gives us scale through centralised business practice including trial management, feasibilities from sponsors, marketing and accounting. Our staff comprise of: experienced, highly trained research nurses, trial coordinators and support staff including: finance, management, IT, phlebotomy, dedicated research pharmacists and regulatory specialists. Our grants team are experts in the management of collaborative group and investigator initiated trials.

Our 2023 name change from Middlemore Clinical Trials to Aotearoa Clinical Trials better reflects our drive for multiple research sites and thriving partnerships the length and breadth of New Zealand, something we are already well on our way to achieving. In 2023 we welcomed Whangarei Hospital as a new partner.

Because we've been working from the heart of a hospital since our earliest days, we have gathered unrivalled insight and experience across a range of disease states and in all Phases of clinical trials. Importantly we have also gained invaluable understanding as to how clinical trials can work alongside and indeed complement service provision in large public hospitals.

Our partnership with Middlemore Hospital in Counties Manukau has taught us how to engage with an ethnically, socially and culturally diverse community who suffer disproportionally from acute and chronic medical conditions.

This gives us a first-hand understanding of the complexities and competing priorities of New Zealand's health system and Te Whatu Ora. Our clinical trial management model can be customised to specific challenges and deployed in multiple sites across the country. For our hospital partners, we aim to remove the financial, regulatory and legal risk while enabling world-class health clinical trials to take place in their regions.

As we focus solely on clinical trials, we recognise the needs and requirements of the sponsors and the researchers.

Importantly we know how to engage with potential participants within our diverse local community. We are always interested in developing more partnerships with new sponsors both in device and biopharmaceutical trials.

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Foreword from the Chair

The 2023 financial year was the first in three years not impacted directly by COVID-19 and the restrictions imposed by the New Zealand Government. The previous year saw activity levels pick up in the second half as the rest of the world moved on from COVID-19. This momentum continued into FY23 for the full year and as a result the unit had a record year in terms of commercial revenue, profitability, and a record year overall including in the number of patients benefiting from trials.

The pipeline of enquiries and new trials continues to grow.

Consequently the board and management expect that FY24 will be another good year with further growth in revenue and surpluses that will ultimately be available for investment in further research and other projects for the betterment of health outcomes of the Trust's patients.

Once again this is a credit to the team who have had to quickly adapt. The growth in number of trials also reflects the increasing number of sponsors and CRO's that the organization deals with, and the number of department and researchers that Aotearoa Clinical Trials is partnering with continues to grow also.

In addition, it is pleasing to report that activity in non-commercial or grant funded trials also have stabilized at around historic levels.

In our last annual report we mentioned the formation of Te Whatu Ora and the opportunities that its formation might bring. Those opportunities are now starting to be realised in the form of a relationship agreement signed with Whangarei Hospital, where trials are about to start, bringing the same benefits to those patients, that patients at Middlemore Hospital experience.

In line with the move to partner with additional hospitals and reflecting its relationship with Te Whatu Ora, the Trust changed its name to Aotearoa Clinical Trials Trust during the year, another significant milestone in its development.

The team are looking forward to, in time, welcoming other hospitals to Aotearoa Clinical Trials and sharing the benefits that its model can offer hospitals, clinicians and patients.

The Trust Board would like to again thank the team for their extraordinary efforts this year, with the changes and growth in staffing in the previous year showing benefits and allowing the growth in revenues and patient numbers to occur.

Special thanks must also be made to the core group of physicians whose expertise provides significant support for the Trust's activities, and we also welcome to the physicians at Whangarei to working with Aotearoa Clinical Trials.

Greg Batkin

Chair of Aotearoa Clinical Trials Board of Trustees

The new brand for Aotearoa Cllinical Trials was successfully rolled out in FY23

Dr Edward Watson

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Year in Review from the CEO

In December 2022 Aotearoa Clinical Trials (ACTT) was created - a natural evolution from the entities that preceded it: Middlemore Clinical Trials (MMCT) and the Centre for Clinical Research and Effective Practice (CCRep).

Aotearoa - the Maori name for New Zealand encapsulates our vision to widen our scope of offering clinical trials to other communities throughout the country. During the year we welcomed Whangarei Hospital and the community of Te Tai Tokerau (Northland) into our network of partnering hospitals.

Our focus is on managing clinical trials in public hospitals within Te Whatu Ora (Health New Zealand). For 21 years we have done so in Middlemore Hospital in the Auckland district of Counties Manukau. We have learned the necessary steps and insights to be able to perform more and more successful clinical trials within a busy, service based tertiary hospital.

Additionally, our success has also grown. We again delivered more trials to more people than ever before, breaking the records set in 2022. With record revenues we have increased the number of staff employed by ACTT and have invested heavily in three core areas: staff training, quality and an electronic management system (eClinical) that allows all aspects of our trials to be run electronically. This puts us at the forefront of clinical trial management in New Zealand.

We now work with over 25 hospital departments welcoming dermatology and anaesthetics to the list of therapeutic areas that we work in. As we expand our capability we hope to offer more complex earlier phase trials in many of the therapeutic areas that we work in.

We acknowledge and welcome our partners at Te Whatu Ora (Health New Zealand) and Te Aka Whai Ora (Maori Health Authority). We hope to offer much needed oncology clinical trials to the local community. Counties Manukau, in south Auckland is an ethnically and economically diverse community whose death rates from cancer are considerably higher than their fellow cancer patients in central Auckland -12 kilometres away. Such stark inequality highlights both the current problems of the health service and the need for more clinical trials (and oncologists) to be available to similar communities.

The positive environment created by Mr Chris Harmston- Director of Research at Whangarei Hospital around the advent of more clinical trials to Whangarei Hospital situated in the north of New Zealand is exciting. Our staff are highly motivated to bring as many clinical trials as possible to a regional hospital in New Zealand and to help address both the health inequities found there as well as provide access to cutting edge medical technology.

It has been another great year for Aotearoa Clinical Trials.

This has been possible because of our professional, talented and dedicated research staff who possess a growing array of skills. It is also a result of the great partnerships we have with the over 40 clinical investigators we work with in all departments and the department service managers. Special thanks again to the resident investigators whose particular dedication enables that we always recruit to target and ensure patient safety; Dr John Baker, Dr Ian Rosen, Dr Renate Koops, Dr Joanna Wojciechowska, Dr Aritra Ray and Dr Farid Shaba.

Dr Edward Watson
CEO

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Board of Trustees FY23

Greg Batkin

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

Dr Pete Watson

Pete is a medical graduate of Otago University and then completed specialist training as a Paediatrician. Pete commenced as a Consultant at Counties Manukau Health as a University of Auckland clinical academic in 1996. Pete remained at CMH until 2022 working across Child and Youth Health, Mental Health & Addictions. Pete has held various local, regional and national clinical leadership roles and 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 which he stepped down from in 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 having held clinical and operational leaderships roles in New Zealand Public Health care setting. Originally trained as a pharmacist, Sanjoy also has extensive pharmaceutical sector knowledge and experience. He is also a strong advocate for equity and diversity.

Kevin Wightman

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

Whetumarama Parore

Marama has worked in the New Zealand health sector for over 30 years in a range of Government and non-Government organisations. Marama has worked in roles as the 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. Marama was Director of Māori Health in Healthcare NZ where the focus was on Advancing Equity across Healthcare NZ to support and enhance whanau Māori well-being. An interim role in Te Aka Whai Ora in the Whānau Voice team, then led Marama to Whaikaha – Ministry of Disabled People as Kaihautū – Chief Advisor Māori.
Marama is a member of Te Kāhui Piringa at Te Tāhū Hauora - Health, Quality, Safety Commission and is a Trustee Board member of Whānau Awhina – Plunket.

Michael James

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

Board of Trustees FY23

Greg Batkin

Dr Pete Watson

Sanjoy Nand

Kevin Wightman

Whetumarama Parore

Michael James

5/ Senior Management

Dr Edward Watson
Chief Executive Officer

Dr John Baker
Clinical Director

Karen Carter
Research Operations Manager

Dr Nicola Jackson
Grants Manager

Emani Setefano
Finance Manager

Kate Msiska
Business Manager

Alan Smith
Information Systems Manager

6/ General Performance Dashboard FY23

60
Total Staff

43
Research Staff
includes Nurses, Clinical Trial Coordinators, Phlebotomist and Pharmacists

612
New Trial Participants
New entries into trials FY23

76
Commercial Trials
Total number of Commercial Trials underway in FY23

57
Grant Funded Trials
Total number of Grant funded /Investigator led trials

766
Total Participants
Includes ongoing multi-year trials

20
New Trial Activations
Commercial Trials activated during FY23

179
Commercial Feasibilities
Total feasibilities received during FY23

17%
Reserves Spent
Designated/Restricted Reserves Spent on Research Activities During the year

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$10.8m
Total Revenue

$6.5m
Reserves

>$1m
Amount Granted
Amount granted for local research

7/ Clinical Performance Dashboard FY23

25

Active Department

Number of Hospital Departments we worked with in FY23

40

Active Investigators

Number of Principal Investigators involved in Commercial Trials in FY23

5005

Outpatient Visits

Total outpatient visits during the course of trials in FY23

$1.75m

Money Saved

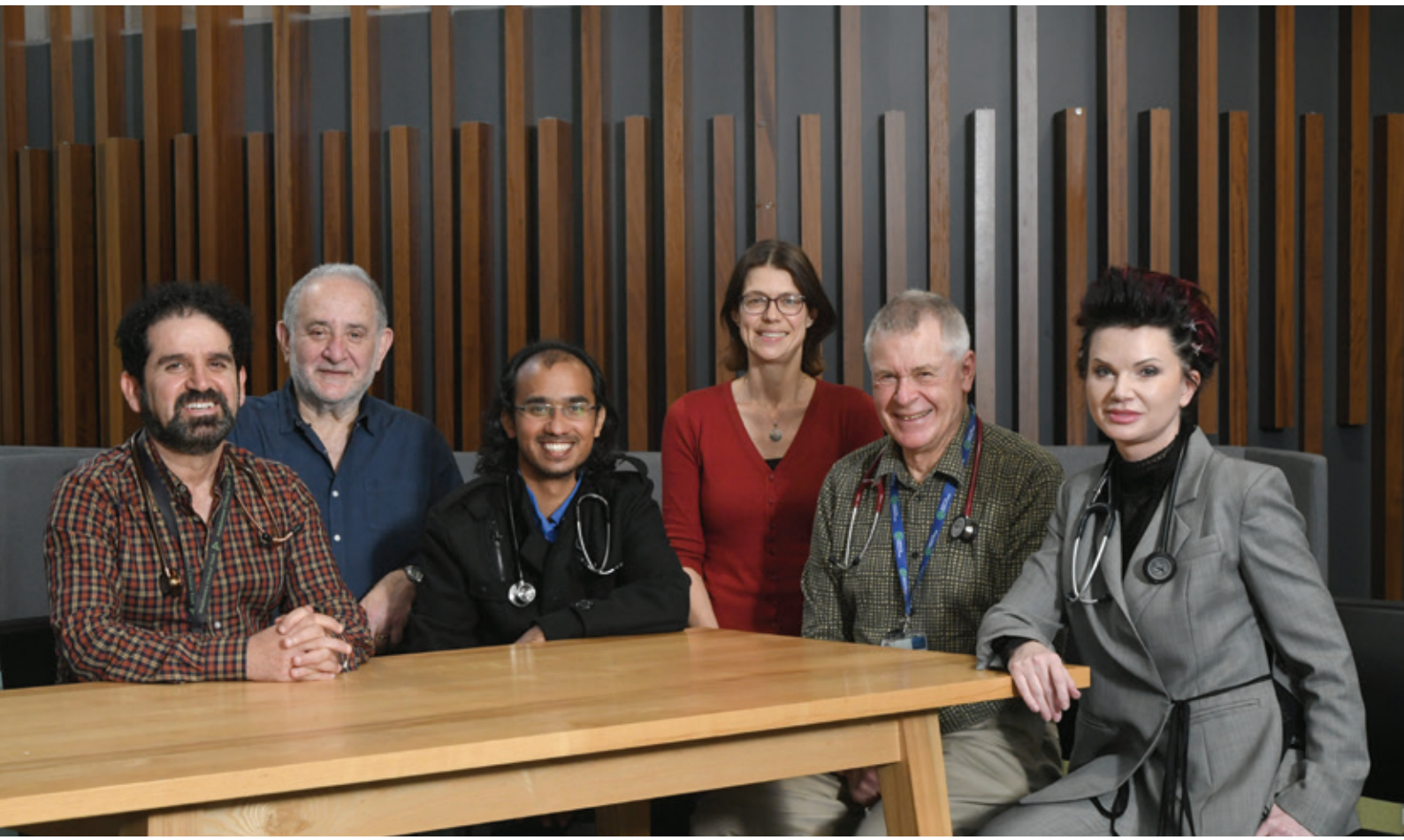
Estimated Money saved by Service Outpatient Visits in FY23

$433k

Community Contributions

Reimbursements to our community for taking part in Clinical Trials in FY23

8/ Resident Investigators



The Resident Investigators of Aotearoa Clinical Trials.

Left to right

Dr Farid Shaba
Dr Ian Rosen
Dr Aritra Ray
Dr Renate Koops
Dr John Baker
Dr Joanna Wojciechowska

9/ What we do – General

Commercial Trials

Commercial trials are one of the core service of Aotearoa Clinical Trials.

Commercial or industry sponsored trials are sponsored by international biopharma companies. They can be Phase I to Phase IV trials reflecting the complexity of the trial design.

COMMERCIAL TRIALS ACTIVITY INCLUDES:

MEDICATIONS

DEVICES

Grant Funded Trials

Grant Funded trials vary in size, length and complexity and are funded by external granting agencies (e.g. Health Research Council), surpluses from commercial trials or other research groups/providers.

COLLABORATIVE GROUP TRIAL

Collaborative Group Trials, typically consist of a group of research leaders working together in their research field. Trials can be regionally, nationally, or internationally based.

INVESTIGATOR INITIATED TRIALS

Typically smaller grant trials, where the investigator conceives the research idea, develops their own protocol and seeks their own funding.

Aotearoa Clinical Trials is New Zealand's largest clinical trial provider

10/
Why we do what we do

At ACTT we believe we can improve health equity in New Zealand by helping to remove barriers to health access and building confidence in world class clinical research.

New Zealand is a land of contrasts and increasingly we see the inequity in our people's access to high quality health care. We bring value to our communities by improving access to clinical trials to address these inequities. We can help participants better understand their health and as a result, achieve better health outcomes. ACTT demonstrates the benefits of research, thereby planting the seeds of confidence in medicines and research that will not only help today's patients but future generations.

We do this by partnering with some of the largest and most innovative biopharmaceutical and medical device companies in the world to bring their novel and innovative therapies to New Zealand.

Through the creation of a network of partnering with public hospitals, we aim to make a lasting difference to the health of all New Zealanders, one community at a time. Our network enables leading health investigators to treat patients in their regions with world-class therapies. We can only achieve this through our effective collaboration with partners right across the New Zealand health sector.

New Zealand is becoming a preferred location for our global sponsors to conduct clinical research. Clinical trials conducted in New Zealand often have a competitive advantage of speed - speed of clinical trial set up and speed of recruitment to target. In addition, at ACTT, we offer a highly experienced research workforce with the passion to improve the health outcomes of our communities through the use of clinical trials. Increasing the number of clinical trials to New Zealand, increases the opportunity of access to novel treatment options to our communities.

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What we do – Commercial

ACTT is a site management organisation with highly trained research staff, with a network of public hospitals. We are dedicated to research- that is all we do.

Our production of high-quality research data means that the investment sponsors have made in us is rewarded. This is demonstrated in sponsor audits which consistently rate us as an international class clinical trial unit.

Speed is of the essence in clinical trials. Returning trial feasibilities, agreeing contracts, assisting the process of obtaining Ethics approvals are all events we ensure occur as swiftly as possible. This means that the study is activated on time.

We pride ourselves in our speed of recruitment of participants to our clinical trials where on average for the last financial year we achieved 106% of the target recruitment

We pride ourselves in the relationship we develop with our participants to ensure they adhere to completing the clinical trials they are involved in. The lasting relationship we build with participants is demonstrated by their enthusiasm to partake in subsequent clinical trials. We value our relationship with CROs and sponsors by delivering the results promised for all trials.

Our Strengths

- Partnership with leading clinicians across 25 hospital departments
- Highly trained and experienced research staff who work within the ICH GCP based guidelines and standard operating procedures of our unit.
- Speed of trial set up from our start up team:
  - Rapid feasibility completion
  - Smooth transition through Institutional Review Board (IRB)/Independent Ethics Committee (IEC) processes
  - Start-up Specialists to ensure timely agreement in budget and contract negotiations
- Recruitment team to develop bespoke recruitment plans for each trial and to ensure recruitment to agreed target
- Access to motivated participants within our diverse community including:
  - Strong partnerships with Middlemore Hospital, Whangarei Hospital and the local Primary Care Organisations
  - Sophisticated social media and advertising channels
- Dedicated research pharmacy and laboratory staff means no delay in IP preparation and sample processing
- Generation of high-quality data for our global partners with the ability to:
  - Generate paperless regulatory and participant files
  - Provide remote monitoring access 24/7

We are driven to improve health outcomes

and reduce health inequity within our communities through world class clinical trials.

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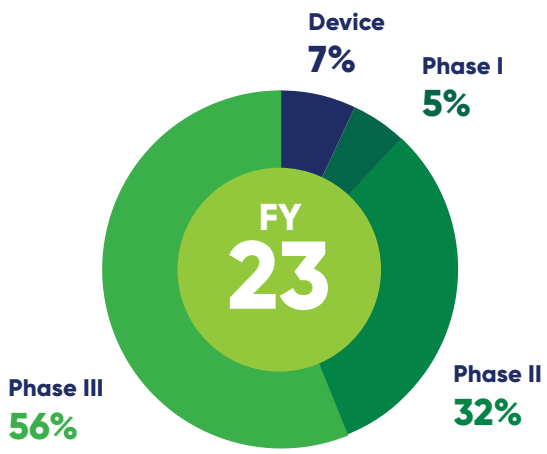
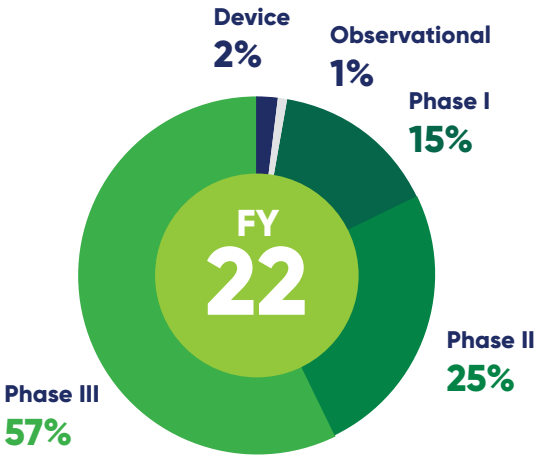
Statistics – Commercial Trials

Commercial Trials By Study Phase/Type





Active Commercial Trials

New Trials Activated

Trials by recruiting departments in FY23

DEPARTMENT	TRIALS	PARTICIPANTS
Cardiology	5	48
Clinical Lipidology	4	11
Dermatology	1	8
Diabetes	2	3
Gastroenterology	6	21
General Medicine	1	31
Haematology	22	60
Hepatology	7	2
Intensive Care	1	1
Neonatal	1	12
Orthopaedics	2	19
Paediatrics	1	14
Radiology	1	1
Renal	2	24
Respiratory	4	15
Rheumatology	8	24
Vaccinology	7	296
Grand Total	75	612

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Feasibilities – Commercial Trials

New feasibilities for clinical trials received

Feasibilities – Engagement by sponsors during FY23

Sponsors FY23

Aptorum International
Arcus Biosciences
Argo Biopharma
Armata Pharma
Arrowhead Research
AstraZeneca
Atriva Therapeutics
Ausper Biopharma
Bausch Health
Bayer HealthCare
BeiGene
Beren Therapeutics
Biointelect
Biotest AG
Boehringer Ingelheim
Brii Biosciences
Cue Health
DevPro BioPharma
Digestome Therapeutics
Dr. Falk Pharma
EQRx
Equillium
Feldan Therapeutics
Genmab
Horizon Therapeutics
Immunovant
Incyte
Insmed
Intra-Cellular Therapies
Ionis
Ipsen
Janssen-Cilag
Karuna Therapeutics
KBP Biosciences
Launch Therapeutics
Merck
Novavax
Olema Pharmaceuticals
Oncternal Therapeutics
Pharmaessentia
ProKidney
Prometheus Biosciences
Roche
Salix Pharmaceuticals
Serodus
Shanton Pharma
Sinovac
Solarea Bio
Sutro Biopharma
Takeda Pharmaceuticals
Teva Pharmaceuticals
The Liver Company
Thermo Fisher Scientific
ViGenCell
Viridia Life Sciences
Wintermute Biomedical
Zhuhai Resproly

CRO's FY23

Advance Clinical
Boehringer Ingelheim
ClinActis
CSI Medical Research
George Clinical
ICON Clinical Research NZ
iProcess Global Research
IQVIA (Quintiles)
Labcorp
Medpace
Novotech
PAREXEL International
PharmaSols
PPD
Premier Research Australia
PSI-CRO
Southern Star Research
Syneos Health NZ

New Trial Feasibilities Received in FY23

	PHASE 1	PHASE I / II	PHASE II	PHASE III	UNKNOWN	TOTAL
Cardiology	-	-	4	4	3	11
Dermatology	-	1	1	5	5	12
Diabetes	-	-	1	1	-	2
Emergency Department	-	-	1	-	2	3
Endocrinology	-	-	4	5	2	11
Gastroenterology	-	-	6	5	1	12
General Medicine	-	-	-	-	3	3
Haematology	-	2	2	11	2	17
Hepatology	-	2	1	6	1	10
Infectious Disease	-	-	1	1	4	6
Intensive Care	-	-	-	1	-	1
Mental Health	-	-	3	2	-	5
Neurology	1	-	2	-	3	6
Oncology	-	3	3	3	5	14
Ophthalmology	-	1	1	1	1	4
Orthopaedics	1	-	-	-	-	1
Paediatrics	-	-	1	2	1	4
Plastics	1	-	-	-	-	1
Renal	-	1	3	5	1	10
Respiratory	-	3	10	2	6	21
Rheumatology	-	-	3	6	2	11
Stroke	-	-	-	1	-	1
Surgery	-	1	-	-	1	2
Vaccinology	1	1	2	3	-	7
Womens Health	-	-	2	-	2	4
						179

14/
What we do – Grants

Aotearoa Clinical Trials also manages non-commercial Grant funded research. Grant funded research 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 drive policy change and enable access to treatments that would otherwise be unavailable for patients in Aotearoa New Zealand.

Many Departments within our partnering hospitals contribute to both Commercial and Grant funded research, and leverage the revenue generated from Commercial research to support investigator-initiated and collaborative group research.

This is a strength of the Aotearoa Clinical Trials model as Research Funds are recycled to support future research activity.

The Aotearoa Clinical Trials dedicated Grants team supports clinical researchers at Middlemore and Whangarei Hospitals to undertake non-commercial grant funded research. In FY23, ACTT supported 57 grant funded clinical trials and research projects. Twelve new studies were activated in FY23 across the disciplines of Paediatrics, Emergency Department, Intensive Care, Diabetes and Surgery. Investigators at Middlemore and Whangarei Hospitals conceived four of these studies. A restructure of the Grants team to include the Grants Manager, PhD-qualified Grant Portfolio Managers and Research Associates has meant that we have been able to support an unprecedented number of funding applications during FY23 that we hope to see activated over the coming year.

Research Highlights:

Funders of Grant Research

- Biomarkers and Future DKD (Dr. John Baker- Endocrinology) –Fisher and Paykel Healthcare Foundation
- ASCOT (Dr.Susan Morpeth – Infectious Disease) – Health Research Council
- SNAP (Genevieve Walls – Infectious Disease) Health Research Council
- AI and Keratoconus (Dr. Rasha Altaie - Ophthalmology) – Potter Masonic Trust
- PICASSo (Mr.Jon Mathy- Plastic Surgery) – Health Research Council
- Resveratrol (Dr. Conroy Wong - Respiratory) – Health Research Council
- Adolescent Bariatric study (Dr.John Baker and Dr.Brandon Orr-Walker- Endocrinology) –Potter Masonic Trust and Perpetual Guardian Trust
- Intravenous Antibiotic Duration for Children with Bronchiectasis (Dr.Cass Byrnes -Paediatric) –Health Research Council

Growth in ED Research

Research in the Emergency Department (ED) at Middlemore Hospital has grown significantly over the last year. The ED Research Team (Te Tira Rangahau), led by Dr Eunicia Tan and supported by the Grants team, has grown to include six highly skilled Research Nurses, contributing a total of 2.6 FTE to research. The ED is currently recruiting participants to five clinical trials, all of which are grant funded through collaborative links with the Medical Research Institute of New Zealand

(MRINZ), Murdoch Childrens Research Institute, and the University of Waikato via the Paediatric Research in Emergency Departments International Collaborative (PREDICT) or New Zealand Emergency Medicine Network (NZ EMN).

These trials are either observational studies 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. Dr Eunicia Tan is the lead investigator for all but one of the six studies and is supported by ED Research Doctors Chris Lash and Andrew Brainard. The team have made significant progress this year to establish themselves as a research intensive Department – the results of which are evident in the high levels of recruitment obtained. ED Research is expected to grow further over the next year with a new investigator initiated trial seeking funding and new collaborative group studies in the pipeline.

Partnership with Whangarei Hospital

A highlight of FY23 has been the establishment of a research partnership with Te Whatu Ora, Te Tai Tokerau locality based in Whangarei. In the first instance, the Grants team is working with Ass. Prof Chris Harmston (Director of Research, Te Whatu Ora Te Tai Tokerau) to support implementation of research studies via the Surgical Trainee Research, Audit and Trials Aotearoa (STRATA) network. The first study to be implemented via this partnership is the ACCORD study – an audit of the watch-and-wait approach in patients with rectal cancer in Aotearoa New Zealand. Dr Hannah Burden (Grant Portfolio Manager, ACTT) is the Project Manager for ACCORD and is establishing a framework for how we work with STRATA and Whangarei Hospital for future studies. The next STRATA-initiated trial is already in preparation and we expect to further grow grant research through engagement with clinical researchers at Whangarei Hospital over the next year.

Funding awarded for Implicit Bias initiative

Paediatric research at Kidz First Childrens Hospital continues to be the largest portfolio that we manage. Dr Sumudu Ranasinghe (Grant Portfolio Manager, ACTT) is the Kidz First Research Coordinator and works with Dr Adrian Trenholme (Clinical Head Research, Kidz First) to support research within the Department. The Kidz First team is currently recruiting participants to five grant funded clinical trials, but are also contributing data and resource to an additional 12 research initiatives within the Department. One of these initiatives is an investigator initiated Implicit Bias project aimed at identifying and addressing bias's at Kidz First. Dr Adrian Trenholme was awarded funding by the Fisher and Paykel Healthcare Foundation in FY23 to undertake this initiative. The project is supported by the Maaori Child Health Research (MCHR) Collaborative in partnership with Mana Whenua and represents a long-term commitment of staff to address this issue.

PICASSo trial results published in JAMA Surgery

The results of the Prophylactic InCisional Antibiotics in Skin Surgery (PICASSo) trial were recently published in JAMA Surgery (PMC10209827: Effect of Microdoses of Incisional Antibiotics on the Rate of Surgical Site Infections (SSI) in Skin Cancer Surgery). This HRC-funded study was initiated by A/Prof (Hon) Jon Mathy (Plastic and Reconstructive Surgeon) and team from Middlemore Hospital. The prospective randomised clinical trial found that intra-incisional microdosed clindamycin delivered along with local anaesthetic significantly reduces the rate of SSI compared with control (local anaesthetic alone), whereas intra-incisional microdosed flucloxacillin had no significant effect. These results provide robust evidence to inform guidelines regarding SSI prophylaxis before skin cancer

Grant funded trials by department

FY23 Grant funded trials by department at Middlemore Hospital

Allied health	1
Cardiology	3
Diabetes	2
Emergency Care	6
Gastroenterology	1
Haematology	5
Home Health	0
Infectious Disease	2
Intensive care	7
Neonatal	2
Oncology	1
Ophthalmology	1
Paediatrics	17
Plastics	1
Renal	3
Respiratory	5
Womens Health	0
Total Middlemore	57

FY23 Grant funded trials by department at Whangarei Hospital

Surgery	1
Total Whangarei	1
Grand Total	**58**

15/
Highlights of the year

Rebranding to Aotearoa Clinical Trials

Earlier in 2023 we announced a name change, from Middlemore Clinical Trials to Aotearoa Clinical Trials. This pivot was to highlight our drive to create a network of public hospital based clinical trial sites. Aotearoa Clinical Trials' vision is to be a globally regarded clinical trial partner to transform health outcomes for all New Zealanders.

A name change also presented a chance to reinvent the brand. The familiar koru remains the same with a distinctive 3D global appearance which provides global perspective. The additional colours in the outer circle and the way they interact with the koru presents the theme of a world of opportunity.

Adding Whangarei Hospital

We welcome Whangarei Hospital into our network of partnering hospitals. Whangarei Hospital is the largest and core hospital in Northland. Whangarei hospital services more than 190,000 people and has 246 inpatient beds. ACTT is pleased to bring access to novel therapies to another community in New Zealand.

Major Granting Milestone

This year we also reached the milestone of granting more than $1 million during the year to enable departments to perform more clinical trials and in support of investigator initiated trials.

Increased Capability

As ACTT continues to grow, the demand for technological advances and specialised roles increases. These changes enable the expansion of our abilities to perform clinial trials.

eClinical

In 2023, ACTT set up their first trial managed totally electronically and paperless using eSource and eDocs. This allows for much higher quality of source data and greater efficiency allowing for remote monitoring, PI sign off and even eConsenting.

Marketing and Recruitment Specialist role

To promote ACTT internally and externally and focus on meeting recruitment targets.

Quality Manager role

To ensure ACTT continues to have best practise in the provision of quality systems, internal audits and standard operating procedures.

Training and Education Manager role

Vital in our quest to create a world class clinical trial unit and ensuring all who work in clinical trials receive appropriate training.

New Record Set for Clinical Trials Delivered

- BEVLIEVE trial over recruited our target by 40%
- Neonatal RSV only site in New Zealand that recruited and randomised to the target
- Flex-Up – First Patient Visit 3 hours from activation
- E.mbrace – the top recruiting site in New Zealand, ACTT were invited to talk about recruitment strategies at the Global Investigator Meeting

16/
Benefits to the Community

Aotearoa Clinical Trials partnership with Middlemore Hospital and Whangarei Hospital allows for increased access to clinical trials to our partnering communities: Counties Manukau and Te Tai Tokarau (Northland).

The benefits of access to clinical trials for the communities include:

Personalisation of care

Hospital or GP clinic visits can feel rushed and impersonal. In contrast, time is not the focus of clinical trials but building a relationship with specialist nurses, coordinators and doctors. It is important for the patient to feel heard. This leads to better understanding by the patient of their medical condition and greater adherence both to the treatment visits and compliance with the medical treatment.

Better Health outcomes

Being part of a clinical trial can lead to better health outcomes than what is otherwise experienced receiving standard of care. In a study performed at Middlemore Hospital patients on interventional diabetic and cardiovascular clinical trials had a 55% reduction overall in death over the 3 years studied and an 80% decrease in cardiovascular related deaths when compared to the patients receiving standard treatment.

Earlier access to modern medicines and treatments

The New Zealand government has very tight restrictions on novel medications. This means often the only way patients can access leading edge medical advancements for their disease is through clinical trials. Some medicines that are not funded by the government agency PHARMAC can be hugely expensive. However, a participant receiving the medicine through a clinical trial normally receives the medicine free of change.

Access to dedicated research doctors and nurses

Early access to novel treatments and better health outcomes is also a driver for both doctors and nurses to be involved in clinical research as part of what they offer their patients. Hospital departments that have a strong research culture tend to attract high quality staff. These staff acknowledge the opportunity to offer their patients more care options that can be available through clinical trials and to learn about treatments other than what is standardly available.

Addressing Health inequity

Health inequality is linked to economic factors, social deprivation, and access to healthcare. A significant number of our community in Counties Manukau and Whangarei have poorer outcomes than other parts of the country. This is particularly important for the Pasifika. Maaori and Indian communities in Counties Manukau. Clinical trials can provide faster access to care and importantly to novel treatments often years in advance as to potentially when they otherwise would. These factors combined with better health outcomes for participants can help address some of the barriers to better health equity.

Community Reimbursement

In the last 12 months ACTT has contributed over $432,000 in reimbursements to participants in the communities we work in. This is to help reduce some of the barriers to accessing healthcare such as travel to and from the hospital, time away from work or parking at the hospital. This enables appointments to occur on time and better adherence to clinical trial protocols.

Community Days

ACTT, in collaboration with Middlemore Foundation, attended Community Days which provided an opportunity to engage with the community we serve and talk about improving health outcomes. ACTT attended "Our Rewa Our World" in Manurewa and Kaiaua Community event. Being present in the public showed how important it was to also get out into our community and spread awareness about clinical trials and access to novel treatment options to better their health.

Pictured: Emani Setefano, Lyle Smith (Middlemore Foundation), Divya Patel and Sharon Cheung

17/
Participation highlights

SOURCE: Participant surveys

	2023	2022
Rate your overall satisfaction with ACTT	Excellent **83%**	Excellent **84%**
How would you rate your overall experience in being involved in clinical trial?	Excellent **77%**	Excellent **86%**
Rate the friendliness of our staff to you and your whanau	Excellent **90%**	Excellent **90%**
Rate the caring concern of our staff to you and helping you understand your condition	Excellent **88%**	Excellent **90%**
Would you recommend being involved in clinical research to others?	Yes **99%**	Yes **92%**

What was the main reason for participating in a clinical trial?

My doctor recommended it
13%

To help future generations
78%

To learn more about my condition
17%

To gain access to modern medicines
42%

The adoption of eClinical means ACTT is at the forefront for Clinical Trial management

18/ Patient stories

Banson Y.
Topic: Dermatology

How did you find out about the clinical trial?

I heard about this clinical trial from Dr Paul Jarrett. I was referred back to him after I had a excessive serious condition of eczema. I've had eczema all my life and it was controlled for a period of time, except when I caught COVID, I suspect with my immune system becoming quite compromised and I went to my local GP and they referred me back to Dr Jarrett.

During my treatment the conversation about a clinical trial was raised, that could potentially improve my condition. At that point, the severity of my eczema and that I have lived with it all my life, I was hopeful that a clinical trial would able to provide me some type of long term relief that I have been missing for a long period of time.

Tell me about your experience being on a clinical trial

The process has been very smooth, everything from people here and the introduction of what was expected from myself and what will be conducted has been very informative. there has been no point where I have felt out of my depth, purely because there has always been someone to guide me as to what the next step is going to be. This clinical trial has been a good experience, I don't regret, obviously, coming on board.

Would you recommend it

For this specific clinical trial, the answer is, obviously yes. For myself it is a resounding success. I have used all sorts of treatment throughout my life, a heavy dose of steroid creams, immunosuppressant with varying degrees of success. This clinical trial has proven to be more successful than I could have ever dreamed. If anyone has as similar condition to myself, and they haven't had success with creams or other treatments, I highly recommend this clinical trial.

Any other comments you would like to make?

I don't have any other comments. I have high praise for the clinical trial and how it's been conducted and everyone involved. The only regret is this wasn't made available sooner, if this goes to market, there are a lot of people like myself who will benefit greatly from this.

Harwinder K.
Topic: Lipidology

How did you find out about the clinical trial?

My doctor, Dr Cam Kyle told me. After a few episodes of pancreatitis, (due to a genetic condition that causes high blood lipids) he found that the standard treatment was not the solution so he started looking for other options, so this is how I found out about the clinical trial.

Tell me about your experience being on a clinical trial

I think it's been great, most importantly I didn't get any pancreatitis since being on this trial so this is wonderful. Everyone has been so helpful. I love Dr John Baker, he is very helpful and is very open with conversations. Indu the trial co-ordinator has been amazing. So it has been a good experience.

Would you recommend it

Yes of course, if someone has a problem for their condition and they couldn't find a solution it is not a bad option. Everybody is different, so you should consult with a medical expert. Of course if you are healthy and you can take any kind of medication, it is a good place to be.

Any other comments you would like to make?

I hope this medicine goes through the pathway of success. Because there are very few people in the world with this genetic disorder and they may not get the chance to be on a clinical trial and get the benefit of this medicine. I really wish this becomes a success, and everyone who is suffering will get to experience the benefit of this medicine.

Harwinder K.

Gerard S.
Topic: Haematology

How did you find out about the clinical trial?

I had finished my blood tests and had 2 transplants, then I finished my second course of standard care chemotherapy which didn't do that much. I was going to a clinic and importing standard care, from India and getting it put into me. Then my doctor in East Tamaki, said there was a trial coming up. My doctor works here (Middlemore Hospital) and has a clinic in East Tamaki, my condition wasn't under control or working that well, and now I have been on the trial for 5 and a half years, and it's just been working beautifully.

Tell me about your experience being on a clinical trial

It was very nice; the people are lovely. Drug wise, chemo isn't as bad as people think it is. It's not a very drastic chemo, it feels similar to a hangover the next day, just a bit draining. I went from having 6 weeks to live to I'm not going to die. I found coming to the hospital easy, easy to get around, parking is good, easy to come in and do it and I don't mind getting the needles.

Would you recommend it

If you're sick. Most definitely. It's getting the modern drugs. The usual standard care is pretty basic.
Its good, clinical trials are good if you get a chance to get on one.

Any other comments you would like to make?

Once you're on a clinical trial, you can talk about what is coming up next. When you have terminal cancer, it's not terminal its more just a matter of time. Just take any clinical trial you can get.

Gerard S.

Don A.
Topic: Lipidology

How did you find out about the clinical trial?

The way it started for me is that I saw my doctor for annual check-ups and amongst some results were high cholesterol readings. Then the next thing I was approached by you guys (ACTT) to see I was interested in a trial. I came in and they took my blood test and my cholesterol this time was too low so I couldn't be on it. A year later, another trial came up and I got a phone call back as I was eligible and if I was interested, and now I'm on the trial. My cholesterol has always been high, so this drug I am taking is designed to reduce it.

Tell me about your experience being on a clinical trial

The people, I can't rate them highly enough. They're very friendly, I've got to know them like Dracula down the hallway, we (Me and Lara) joke about it.

I gave plasma, because as far as I'm concerned, my plasma would go towards helping save someone's life. If this works out and if this drug helps other people, I'm all for it.

Also this is selfish, the fact that I get a free ECG, a doctor check-up, checks my lungs it's like a free physical and it's all part of the trial, is great.

Would you recommend it

Yes. I mean its each person decision. If I'm doing it, I'm explaining why I'm doing it and then it's their decision to be on one. If it helps someone else out, then ultimately I'm all for it.

Any other comments you would like to make?

All good. I'm happy to give my time to do something useful.

Don A.

19/
Areas of research by department

Haematology

The Haematology Department has had another outstanding year in research, receiving the most feasibilities of any department and performing the most clinical trials. The department is active in both commercial and grant-funded research and their portfolio covers a range of haematological diseases. There are ongoing clinical trials investigating treatments for myelofibrosis, B-cell non-Hodgkin's lymphoma, chronic lymphocytic leukaemia/small lymphocytic lymphoma, multiple myeloma and more. 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.

Clinical Lead: Dr Sharon Jackson

CM Health

Dr Gordon Royle (Investigator)

Dr James Liang (Investigator)

Dr Kirsty Marshall (Investigator)

Dr Samar Issa (Investigator)

Dr Sharon Jackson (Investigator)

Dr Jian Li (Investigator)

22 COMMERCIAL TRIALS

5 GRANT FUNDED TRIALS

Clinical Lipidology

Clinical lipidology involves the diagnosis and management of lipid (cholesterol) and lipoprotein disorders. Dr John Baker (Clinical Director of ACTT) is lead investigator for these trials. The current research portfolio includes treatments for mixed dyslipidemia and familial chylomicronemia syndrome. Familial chylomicronemia is a rare genetic disorder that affects 1-2 individuals per million and ACTT were able to recruit a patient to this study.

ACTT Research Team

Dr Joanna Wojciechowska (Investigator)

Dr John Baker (Investigator)

4 COMMERCIAL TRIALS

11 GRANT FUNDED TRIALS

Emergency Department

The Emergency Department has had a successful year with multiple ongoing trials led by Dr Eunicia Tan and Dr Chris Lash. Dr Eunicia Tan has been very active in increasing research in the department and is the lead investigator in multiple trials due to start this year. The current research portfolio includes treatment for infants with bronchiolitis, investigating recovery from concussion in children and adolescents and investigating the occurrence of adverse events following emergency department visits.

Clinical Lead: Dr Matthew Clarke

CM Health

Dr Eunicia Tan (Investigator)

Dr Chris Lash (Investigator)

6 GRANT FUNDED TRIALS

Gastroenterology and Hepatology

With 13 ongoing trials in the last year, the Gastroenterology and Hepatology Department has had another busy year. The department's portfolio is made up of predominantly commercial trials, with a significant focus on therapies for chronic hepatitis B and NASH (non-alcoholic steatohepatitis). Other current research interests of the department include NAFLD (non-alcoholic fatty liver disease), Cirrhosis and Eosinophilic Esophagitis.

Clinical Lead: Dr Kumudith Ekanayaka

CM Health

Dr Ashok Raj (Investigator)

Dr Paras Garg (Research Fellow and Sub-Investigator)

Dr Tien Huey Lim (Investigator)

Infectious Diseases

The Infectious Diseases Department is currently engaged in two continuous research projects funded by grants. Dr. Susan Morpeth is at the helm of ASCOT, which is focused on exploring potential treatment approaches for COVID-19 patients hospitalized without the need for intensive care. Simultaneously, Dr. Genevieve Walls is leading the SNAP study, which seeks to determine how various clinical interventions impact the overall 90-day mortality rate in cases of Staphylococcus aureus bloodstream infection.

Clinical Lead: Dr Chris Luey

CM Health

Dr Genevieve Walls (Investigator)

Dr Susan Morpeth (Investigator)

Dr Christopher Hopkins (Sub-investigator)

Dr Christopher Luey (Sub-investigator)

Dr David Holland (Sub-investigator)

Dr Stephen McBride (Sub-investigator)

Intensive Care Unit

Over the past year, the ICU Department has been actively conducting numerous continuous clinical trials. Dr. Tony Williams has been at the forefront of overseeing all these trials within the department, with valuable assistance from research nurse Rima Song. The department's research primarily centers around the comparative analysis of various interventions related to blood infections, community-acquired pneumonia, and resuscitation. The overarching goal is to diminish mortality rates and enhance positive outcomes for critically ill patients.

Clinical Lead: Dr Tony Williams

CM Health

Dr Tony Williams (Investigator)

Rima Song (Research Nurse)

Vivian Lai (Research Nurse)

Dinurag Girijadevi (Research Nurse)

13 COMMERCIAL TRIALS | **1** GRANT FUNDED TRIALS

2 GRANT FUNDED TRIALS

1 COMMERCIAL TRIALS | **1** GRANT FUNDED TRIALS

Neonatal

Primarily dedicated to research funded by grants, the Neonatal Department has enjoyed another successful year. Presently, the department is actively conducting ongoing trials in several areas, including the development of an RSV (respiratory syncytial virus) vaccine, standard care protocols for neonates, and the development of a medical device for respiratory assistance.

Clinical Lead: Dr Richard Matsas

CM Health
Dr Elizabeth Nevill (Investigator)
Dr Julena Ardern (Investigator)
Dr Mike Meyer (Investigator)

Paediatrics

The Pediatric Department primarily engages in trials funded by grants, and it has seen remarkable success this year with a total of 16 ongoing trials. Led by clinicians from Kidz First Children Hospital, these trials are concentrated on illnesses that are widespread within our local community, such as RSV, bronchiolitis, bronchiectasis, influenza, and acute rheumatic fever.

Clinical Lead: Dr Richard Matsas

CM Health
Dr Adrian Trenholme (Investigator)
Dr Jocelyn Neutze (Investigator)
Dr Mike Meyer (Investigator)
Dr Rachel Webb (Investigator)
Dr Tim Hill (Investigator)
Dr Catherine Brynes (Investigator)

Renal

The Renal Department fosters an exceptionally inclusive research environment, with the majority of its clinicians actively participating in research endeavours, encompassing both commercial and grant-funded trials. Their ongoing research portfolio encompasses areas such as hypertension management, chronic and end-stage kidney disease treatment, and the exploration of standard care protocols for dialysis patients.

Clinical Lead:
Dr Jamie Kenrick-Jones

CM Health
Dr Hari Talreja (Investigator)
Dr Jamie Kendrick-Jones (Investigator)
Dr Kalpa Jayanatha (Investigator)

1	2	1	17	2	3
COMMERCIAL TRIALS	GRANT FUNDED TRIALS	COMMERCIAL TRIALS	GRANT FUNDED TRIALS	COMMERCIAL TRIALS	GRANT FUNDED TRIALS

Respiratory

The Respiratory Department has experienced another busy year. Their research portfolio, comprising trials supported by both commercial sources and grants, is centered around exploring treatments for COPD (chronic obstructive pulmonary disease), asthma, bronchiectasis, Idiopathic Pulmonary Fibrosis (IPF), and Progressive Fibrosing Interstitial Lung Disease (PF-ILD). Additionally, a research study funded by a grant, under the leadership of Dr. Conroy Wong, is delving into the clinical attributes of bronchiectasis in both adults and children, with the aim of gaining a deeper understanding of the disease and its potential treatment options.

Clinical Lead: Dr Stuart Jones

CM Health

Dr Conor ODochartaigh (Investigator)
Dr Conroy Wong (Investigator)
Dr Elaine Yap (Investigator)
Dr Stuart Jones (Investigator)
Dr Paul Dawkins (Investigator)
Dr Leon Chang (Sub-investigator)
Dr Leon Huang (Sub-investigator)

15 COMMERCIAL TRIALS

5 GRANT FUNDED TRIALS

Rheumatology

The Rheumatology Department's research endeavors encompass a broad spectrum of medical conditions, such as gout, systemic lupus erythematosus, rheumatoid arthritis, polymyalgia rheumatica, psoriatic arthritis, axial spondyloarthritis, and giant cell arteritis. The department has experienced a highly active and fulfilling year. These trials frequently offer patients opportunities to access treatments that may not be readily available in New Zealand, potentially leading to life-altering improvements in their conditions.

Clinical Lead: Dr Sunil Kumar

Research Team

CM Health

Dr Sunil Kumar (Investigator)
Dr Mark Sapsford (Investigator)

8 COMMERCIAL TRIALS

Vaccinology

Our vaccine trials have maintained their positive momentum, with ongoing recruitment for studies aimed at developing vaccines against COVID-19, influenza, RSV, urinary tract infections, and staphylococcus aureus infections.

Research Team

ACTT

Dr Ian Rosen (Investigator)
Dr Joanna Wojciechowska (Investigator)
Dr John Baker (Investigator)
Dr Renate Koops (Investigator)
Dr Aritra Ray (Sub-Investigator)

CM Health

Dr Justine McCullum (Sub-Investigator)
Dr Katherine Rix-Trott (Sub-Investigator)
Dr Robert Cortesi (Sub-Investigator)
Dr Tim Hill (Sub-Investigator)
Dr Zahra Al-Khudairi (Sub-Investigator)
Lucy Lu (Research Midwife)
Sauiluma Tiatia (Research Midwife)
Amanda Retter (Research Nurse)
Gail Spence (Research Nurse)
Shirley Lawrence (Research Nurse)

7 COMMERCIAL TRIALS

20/
Staff Awards

Left to right with awards

Juliet Tinone
Research Nurse

Certificate of excellence

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

Alan Smith
Information Systems Manager

The ACTT Award Recipient 2023

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

Rebecca McMillan
Research Team Lead

Certificate of excellence

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

ACTT has trialled and adopted eClinical for 100% paperless trial management

21/
Spotlight on Infectious Diseases

Department spotlight – Infectious Diseases

Infectious Diseases constitutes a medical specialty focused on diagnosing and treating illnesses caused by infections within the human body. Such infections can be caused by bacteria, viruses, fungi, or even parasites and may manifest in community settings or as a result of medical treatments received in a hospital. While many of these ailments are managed by various medical and surgical teams, certain cases necessitate specialized infectious disease expertise.

"Middlemore is a hospital that sees a lot of infectious diseases, and that is related to a number of factors, such as socioeconomic conditions and associated medical conditions.

Middlemore typically sees a higher rate of infectious disease than other parts of the country. An example of this is Staph Aureus bacteraemia, which we look at in the SNAP study" says Dr Genevieve Walls- Infectious Disease physician.

Dr Walls explains the infectious disease context within Middlemore Hospital also encompasses aspects of multi-resistant (to antibiotics) organisms and infection control. Multi-resistant organisms like Carbapenemase-producing Enterobacterales bacteria (CPEs) that are resistant to antibiotics are seen in increasing numbers in particular from overseas in travellers. As the population of New Zealand continues to travel to visit family and friends, the multi-resistant organisms that are common in other parts of the world, are presented back here on our soil and have the potential to spread. Importantly the Infectious Disease Department identify patients with these organisms so prevent spread around the hospital to avoid hospital outbreaks,

The Infectious Disease Department at Middlemore Hospital participates in research which looks to answer important questions which directly impact the clinical management of patients.

Key infections focussed on to date include:

a) Staphylococcus aureus bacteraaemia

- SNAP study (ongoing) – see blurb from Genevieve Walls below
- CAMERA 2 study (complete) – Australasian, randomised controlled trial looking at the impact of adding a beta-lactam antibiotic to conventional treatment of Methicillin resistant Staphylococcus aureus bacteraemia

b) COVID-19 and community acquired pneumonia

- ASCOT-ADAPT study and REMAP-CAP (ongoing) – see blurb below

c) Prosthetic joint infections

- PIANO study (combined research with orthopaedics - complete) - Australasian prospective observational study of prosthetic joint infections. This study has informed an upcoming PJI-ROADMAP study (prospective), an international RCT looking at both surgical strategy and antibiotic therapy for prosthetic joint infections which Counties is applying to participte in.

d) Native joint septic arthritis

- ASASA (complete) – largest, retrospective observational study of native joint septic arthritis in the world

e) Gram negative bacteraemia

- MERINO (complete) – International RCT comparing different beta-lactam antibiotic options for Gram negative bacteraemia secondary to ESCAPPM organisms

f) Antimicrobial stewardship

- BALANCE (combined research with ICU - complete) – 7 vs 14 days antibiotic duration for bacteraemias in ICU
- TAKING THE PISS (complete and ongoing) – diagnostic stewardship observational and interventional studies looking at guiding appropriate requesting for urine culture to avoid unnecessary and potentially harmful antibiotic prescribing.

See page 38.

Back row left to right: Susan Taylor, Tim Cutfield, Susan Morpeth, Chris Luey
Front row left to right: Veronica Playle, Stephen McBride, Chris Hopkins, Genevieve Walls, Natasha Pool

g) Clostridium difficile

- See below from faecal microbiota transplant study for C. difficile

h) Strongyloidiasis (complete – in write up) – retrospective study of strongyloides screening and treatment in Te Whatu Ora-Counties Manukau by Dr Tim Cutfield.

The SNAP Study

Dr Genevieve Walls

NZ has one of the highest rates of S. Aureus bacteraemia (SAB - bloodstream infection) in the developed world. SAB has a mortality of 15-20%, and disproportionately affects Māori, Pacific peoples, the very old, and the very young. There is significant variability in the treatment of SAB worldwide, and treatment variability is associated with poor outcomes. The SNAP (Staphylococcus aureus Network Adaptive Platform) trial is a pragmatic randomised clinical trial whose Bayesian design allows the assessment of multiple SAB treatment options in parallel.

SNAP is now the largest randomised trial of SAB treatment ever conducted. There are over 70 active sites around the world. It is a whole-of-life trial, enrolling neonates, children and adults. Middlemore Hospital is the lead NZ site (NZ PI Dr Genevieve Walls, Infectious Diseases physician) and the highest recruiting site internationally. The nine NZ sites currently open (including two paediatric hospitals) have contributed around 20% of global enrolment so far. The paediatric component of SNAP, SNAP-PY, is led in NZ by Dr Rachel Webb (KidzFirst Children's Hospital). Dr. Hannah Burden from ACTT is the NZ SNAP/SNAP-PY project manager. As well as answering the key SAB treatment questions, the SNAP platform allows the integration of sub-studies, sharing of data and bacterial isolates, and promotes local and international collaboration.

The NZ SNAP team has also just been awarded a grant by Te Niwha Infectious Diseases platform to pursue a SNAP sub-study looking at the pharmacokinetics of oral antibiotics and probenecid in patients being treated for SAB.

ASCOT-ADAPT and REMAP-CAP studies

Dr Susan Morpeth and Dr Tom Hills

ASCOT ADAPT, the Australasian COVID-19 Treatment Adaptive Platform Trial, is a collaborative, international, investigator-led pragmatic platform for randomised clinical trials for the optimised management of patients hospitalised with COVID-19. ASCOT ADAPT has run an antibody domain, looking at convalescent plasma; an anticoagulation domain, assessing prophylactic, therapeutic and an intermediate dose of anticoagulation; and an antiviral domain, evaluating nafamostat mesylate as an antiviral agent in the treatment of COVID-19.

The platform is led internationally from the Doherty Institute in Melbourne, and in New Zealand by Dr Susan Morpeth, Infectious Diseases Physician and Clinical Microbiologist at Middlemore Hospital. Dr Hannah Burden of Aotearoa Clinical Trials is the program manager. ASCOT evaluates therapies for patients who are unwell enough to need admission to hospital but not the critically unwell who are admitted to the Intensive Care Unit; these patients are studied under REMAP-CAP, the Randomised Embbeded Multifactorial Platform trial of severe Community-Acquired Pneumonia. ASCOT and REMAP-CAP are working together both internationally and in New Zealand and are planning a head to head comparison of nirmatrelvir-ritonavir and remdesivir among patients admitted to hospital with COVID-19.

Taking the Piss studies

Dr Chris Hopkins

URINE CULTURE DIAGNOSTIC STEWARDSHIP

Frequently urine cultures are sent for patients who do not have symptoms consistent with urinary tract infection (UTI). Many people will have 'positive' results (i.e. growth of bacteria) even though this is not making them unwell. This result can often trigger a clinician to give antibiotics despite evidence showing this is harmful with no benefits.

"Taking The Piss" is an ongoing project led by Infectious Disease Department at Middlemore Hospital that aims to improve the testing of urine cultures for UTI, to ensure this is only done for patients with symptoms of UTI. An initial audit showed that at least 41% of adult urine cultures were sent in patients with no UTI symptoms. Current research projects include a qualitative study examining clinicians' rationale, and a pilot trial of electronic requesting with in-built clinical decision support.

C. difficile study

Dr Chris Hopkins

C.DIFFICILE DIARRHOEA

C.difficile Diarrhoeal Infection (CDI) often recurs after treatment with an antibiotic. In that case there is growing evidence that a faecal transplant dramatically reduces the risk of further recurrence. This can be given in several different ways, but giving it in capsule form is by far the most accessible, convenient, safe and palatable option. But these are not currently available in NZ. Previously faecal transplant capsules have only been trialled following a further course of antibiotics.

The Infectious Disease Department at Middlemore Hospital are involved in a University of Auckland-led trial of faecal transplant capsules for treatment of recurrent CDI, with or without a course of antibiotic first. The results are likely to inform future treatment options for this difficult disease.

At Middlemore Hospital we work with a population that disproportionally suffers from infectious diseases. The research we can do provides results that are relevant for our community. This is really important for us in South Auckland and New Zealand as a whole. Dr Walls concludes, "the Infectious Disease department is an enthusiastic group of people that are keen to do local research that is also a really collaborative speciality. Collaboration with other specialities to answer important questions to ensure the valuable results are directly applied to our community".

Dr Walls acknowledges the collaboration with Aotearoa Clinical Trials as being really productive in their clinically relevant research and the support and advice has been a significant helping hand.

ACTT now employs three Clinical Trial Pharmacists

22/
Trust Outcomes and Granting

Trusting Outcomes

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

Departmental Breakdown of Granting from Designated / Restricted reserves FY23

	$
Conferences	103,361
Publication	19,550
Research Fellow	614,591
Research Nurse	218,145
Misc.	46,663
Grand Total	**1,002,310**

As of 30 June 2023, from the designated reserves ACTT for the first time has spent $1,002,310 on Granting. 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

$1,566,241

($1,192,618, 30 June 2022).

ACTT has a dedicated Infusion Suite just for clinical trials

Granting spend summary from Designated/Restricted Reserves in FY23

DESIGNATED + RESTRICTED RESERVE	OPENING BALANCE	GRANTING	% OF OPENING	CLOSING BALANCE
Cardiology Fund	1,167,304	26,791	2%	-
Cardiology Capex Fund	416,132	70,928	17%	-
Cardiac Cath Lab Nurses Education Fund	19,321	-	-	-
Cardiology Designated Reserve Fund (*See Note)	1,601,221	-	-	1,601,221
Dermatology Research Fund	27,535	9,369	34%	22,318
Diabetes Fund	59,017	1,993	3%	57,286
Emergency Care Clinical Research & Education	42,213	-	-	44,676
Gastro Research Fund (incls Hepatology)	181,562	29,500	16%	430,787
Haematology Research & Special Purposes Fund	911,681	10,107	1%	1,198,917
Home Health Fund	20,334	-	-	31,650
Intensive Care Unit Fund	558,621	93,037	17%	525,353
Infectious Diseases Research and Education Fund	114,439	477	0%	144,477
Kidz First Research Development fund	1,153,453	388,175	34%	922,004
Spinal Unit	24,319	-	-	24,428
Microbiology Fund	17,843	-	-	17,924
Neonatal Research	100,445	72,534	72%	96,718
Oropharyngeal Department Fund	6,924	-	-	8,742
Hand and Upper Limb Research Fund	149,865	43,245	29%	148,534
Radiology Research Fund	1,703	-	-	15,222
Renal Fund	93,554	29,500	32%	78,112
Respiratory Research Fund	582,423	16,984	3%	578,765
Rheumatology Research Fund	245,579	31,337	13%	448,194
Stroke Outcomes Fund	50,920	-	-	51,149
Womens Health Fund	2,372	-	-	5,657
AT&R Research Fund	289	-	-	289
CIU Education Fund	-	-	-	-
Anaesthetics & Surgical	5,000	-	-	5,000
Orthopaedics	74,138	178,333	241%	34,400
Acute Allied Health	1,950	-	-	3,875
Ophthalmology	-	-	-	13,142
Plastics	3,000	-	-	3,000
Midwifery	1,300	-	-	1,300
Oncology	-	-	-	-
General Medical	7,484	-	-	-
ARHOP	-	-	-	13,550
	6,040,719	**1,002,310**	**17%**	**6,526,691**

* This fund is an amalgamation of the previous Cardiology funds

23/
Medical Publications

Publications/FY23

Aoyama, T., Alexander, T., Asadi, S., Harding, J. E., Meyer, M. P., Jiang, Y., . . . Group, D. S. (2023). **Determinants of handgrip strength at age 2 years in children born moderate and late preterm and associations with neurodevelopmental outcomes.** Early Hum Dev, 180, 105750. doi:10.1016/j.earlhumdev.2023.105750

Brandon, R., Jiang, Y., Yeu, R. Q., Tweedie-Cullen, R., Smallman, K., Doherty, G., . . . Murphy, R. (2022). **Stratified glucose-lowering response to vildagliptin and pioglitazone by obesity and hypertriglyceridemia in a randomized crossover trial.** Front Endocrinol (Lausanne), 13, 1091421. doi:10.3389/fendo.2022.1091421

Clements, J., Christensen, P. M., & Meyer, M. (2022). **A randomised trial comparing weaning from CPAP alone with weaning using heated humidified high flow nasal cannula in very preterm infants: the CHiPS study.** Arch Dis Child Fetal Neonatal Ed. doi:10.1136/archdischild-2021-323636

Davis, W., Duque, J., Huang, Q. S., Olson, N., Grant, C. C., Newbern, E. C., . . . Azziz-Baumgartner, E. (2022). **Sensitivity and specificity of surveillance case definitions in detection of influenza and respiratory syncytial virus among hospitalized patients, New Zealand, 2012-2016**. J Infect, 84(2), 216-226. doi:10.1016/j.jinf.2021.12.012

Denholm, J. T., Venkatesh, B., Davis, J., Bowen, A. C., Hammond, N. E., Jha, V., . . . investigators, A. A. (2022). **ASCOT ADAPT study of COVID-19 therapeutics in hospitalised patients: an international multicentre adaptive platform trial.** Trials, 23(1), 1014. doi:10.1186/s13063-022-06929-y

Docherty, K. F., McMurray, J.J.V., Diaz, R., Felker, G.M., Metra, M., Solomon, S.D., Adams, K.F., Böhm M., Brinkley, D.M., Echeverria, L.E., Goudev, A.R., Howlett, J.G., Lund, M., Ponikowski, P., Yilmaz, M.B., Zannad, F., Claggett, B.L., Miao, Z.M., Abbasi, S.A., Divanji, P., Heitner, S.B., Kupfer, S., Malik, F.I., Teerlink, J.R. (2023). **The Effect of Omecamtiv Mecarbil in Hospitalized Patients as Compared with Outpatients with HFrEF: an Analysis of GALACTIC-HF.** J Card Fail. 2023 Sep 6:S1071-9164(23)00316-0. doi: 10.1016/j.cardfail.2023.08.020.

Franklin, D., Babl, F. E., Neutze, J., Craig, S., Oakley, E., Furyk, J., . . . PREDICT, A. P. A. R. I. S. o. b. o. (2023). **Predictors of Intensive Care Admission in Hypoxemic Bronchiolitis Infants, Secondary Analysis of a Randomized Trial**. J Pediatr, 256, 92-97 e91. doi:10.1016/j.jpeds.2022.12.006

Franklin D, B. F., George S, Oakley E, Borland ML, Neutze J, Acworth J, Craig S, Jones M, Gannon B, Shellshear D, McCay H, Wallace A, Hoeppner T, Wildman M, Mattes J, Pham TMT, Miller L, Williams A, O'Brien S, Lawrence S, Bonisch M, Gibbons K, Moloney S, Waugh J, Hobbins S, Grew S, Fahy R, Dalziel SR, Schibler A. (2023). **Effect of Early High-Flow Nasal Oxygen vs Standard Oxygen Therapy on Length of Hospital Stay in Hospitalized Children With Acute Hypoxemic Respiratory Failure: The PARIS-2 Randomized Clinical Trial.** JAMA., 17(329(3)), 224-234. doi:doi: 10.1001/jama.2022.21805

Goh, M., Hollewand, C., McBride, S., Ryan, N., van der Werf, B., & Mathy, J. A. (2023). **Effect of Microdoses of Incisional Antibiotics on the Rate of Surgical Site Infections in Skin Cancer Surgery: A Randomized Clinical Trial.** JAMA Surg, 158(7), 718-726. doi:10.1001/jamasurg.2023.1201

Hardcastle, T., Rasul, U., de Paiva Leite, S., Zheng, K., Donaldson, G., Ahmad, Z., & Morton, R. P. (2022). **The Manukau Salivary Symptoms Score for Assessing the Impact of Sialendoscopy in Recurrent Obstructive Sialadenitis.** Otolaryngol Head Neck Surg, 166(3), 461-467. doi:10.1177/01945998211017444

Kayes, T., Crane, H., Symonds, A., Dumond, J., Cottrell, M., Di Girolamo, J., . . . Levy, M. T. (2022). **Plasma and breast milk pharmacokinetics of tenofovir alafenamide in mothers with chronic hepatitis B infection.** Aliment Pharmacol Ther, 56(3), 510-518. doi:10.1111/apt.17040

McQuilten, Z. K., Venkatesh, B., Jha, V., Roberts, J., Morpeth, S. C., Totterdell, J. A., . . . Tong, S. Y. C. (2022). **Anticoagulation Strategies in Non-Critically Ill Patients with Covid-19.** NEJM Evidence. doi:10.1056/EVIDoa2200293

Nevill, E., Mildenhall, L. F. J., & Meyer, M. P. (2023). **Effect of Breathing Support in Very Preterm Infants Not Breathing During Deferred Cord Clamping: A Randomized Controlled Trial (The ABC Study).** J Pediatr, 253, 94-100 e101. doi:10.1016/j.jpeds.2022.09.025

Priday, A. C., J.; Krishnan, T.; Gillard-Tito, S.; Fielder, A.; McAra Couper, J. (2023). **Women's knowledge, attitudes and access to vaccines in pregnancy: A South Auckland study.** New Zealand College of Midwives Journal(59), 14 - 20. Retrieved from https://doi.org/10.12784/nzcomjnl59.2023.2.14-20

Sundborn, G., Lesa, F., King, G., Vennell, K., Kozak, H., Pickering, K., & Baker, J. (2023). **Empagliflozin and dulaglutide: community awareness project promotes improved access to newly funded medications for Pacific patients with type 2 diabetes.** N Z Med J, 136(1572), 66-74. Retrieved from https://www.ncbi.nlm.nih.gov/pubmed/36958323

Yuen, M. F., Locarnini, S., Lim, T. H., Strasser, S. I., Sievert, W., Cheng, W., . . . Gane, E. (2022). **Combination treatments including the small-interfering RNA JNJ-3989 induce rapid and sometimes prolonged viral responses in patients with CHB.** J Hepatol, 77(5), 1287-1298. doi:10.1016/j.jhep.2022.07.010

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