

ANNUAL REPORT  
2021

20<sup>th</sup>  
anniversary

Te Kohinga Ora  
Middlemore  
Clinical Trials



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## ABOUT US

Middlemore Clinical Trials (MMCT) is a fully integrated specialist clinical trial unit based within one of New Zealand's largest hospitals, Middlemore Hospital in South Auckland.

Established exactly 20 years ago MMCT is an independent charitable trust that administers both commercial and grant funded research on behalf of the local District Health Board, Counties Manukau Health.

At MMCT we believe the best health outcomes are achieved through Clinical Research. We are passionate about bringing health research to New Zealand so that our community can benefit from the opportunity to be part of leading edge science and novel therapies from around the world.

MMCT staff are comprised of experienced, highly trained research nurses, trial coordinators and support staff including: finance, management, IT, phlebotomy, dedicated pharmacist and regulatory

specialists. As we focus solely on clinical trials we understand the needs and requirements of the sponsors and the researchers. Importantly we know how to engage with potential participants within our diverse community.

Working with over 22 departments within Middlemore Hospital we provide a centralized service for all types of trials from Phase I to Phase IV clinical trials. Our fully equipped research unit also contains a dedicated infusion suite which enables us to deliver the highest safety and care for early phase trials.

We embrace the challenge of ensuring that we adopt the latest techniques in human clinical trial research including remote community monitoring, 'virtual' trials, social media recruitment and adaptive trial management.

Due to our size and the number of therapeutic areas we cover we are now one of the largest specialized research units in New Zealand.

**We aim to be the partner of choice for all sponsors wishing to conduct Clinical Research in Australasia.**

# FOREWARD

## From the Chair

The year continued to see the challenges thrown up by COVID-19, with further lockdowns during the year under review and the effect of COVID-19 in other countries effecting the pipeline of new trials, all of which made the year very stop start for the team.

As predicted, the threat of further disruption from COVID-19 was never far away in the year under review (and in the year following too). Nonetheless as in the previous year the team did an extraordinary job of maintaining the care of the participants already enrolled in trials that were underway. An increasing focus on finding new ways of doing things in this environment has resulted in a current project to move Middlemore Clinical Trials to a paperless environment, which amongst other things allows a much more efficient way of working remotely.

Notwithstanding the impact of COVID-19 in other countries, which has affected the start dates for new trials and the pipeline overall for Middlemore Clinical Trials, it is pleasing to report that the pipeline of enquiries and new trials is the strongest it has ever been. Once again this is a credit to the team who have had to quickly adapt from managing the care of trial participants in a challenging environment to initiating a significantly larger number of new trials than normal, all while integrating a significant number of new staff. The growth in number of trials also reflects the increasing number of sponsors and CRO's that the organization deals with, which was reported last year, and is due to the increasing number of departments and researchers that Middlemore Clinical Trials is partnering with.

In addition, it is pleasing to report that activity in grant funded trials is also increasing again towards historic levels.

Whilst COVID-19 has presented Middlemore Clinical Trials with a number of challenges, it is also giving rise to new opportunities with the unit participating in trials for novel vaccines and treatment for COVID-19.

The Clinical Research and Practice Foundation which became known as Middlemore Clinical Trials, was formed on 15th February 2001.

**We are therefore celebrating the organisation's 20 year anniversary, later this year.**

The twelve original trustee's showed significant foresight in the formation of the Trust, as it has become one of the largest specialized research units in New Zealand due to the size and number of therapeutic areas covered.

Whilst the Trust's financial performance overall was lower than originally planned, the strength of the pipeline, the increase in the number of departments and researchers and the hard work and dedication of the team at all levels give the Board confidence the performance in the coming years should show significant improvement.

The board would like to thank the team for their extraordinary efforts again this year, and also make special thanks to the core group of physicians whose expertise provides significant support for the Trust's activities.



**Greg Batkin**  
CHAIR

# TRUSTEES

## & Senior Management Team



**Greg Batkin**

Chair of the Board of Trustees MMCT

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 Middlemore Clinical Trials, Greg is Deputy Chair of Safer Sleep (an anesthetic software company), a large private business based in South Auckland and is Vice Commodore of the Outboard Boating Club of Auckland.



**Dr Peter Watson**

Deputy Chair of the Board of Trustees MMCT  
Chief Medical Officer - Counties Manukau Health  
Deputy CEO - Counties Manukau Health

Peter commenced as a Consultant paediatrician at Counties Manukau Health (CMH) as a University of Auckland clinical academic in 1996. Peter has worked across Child and Youth Health, Mental Health & Addictions and Medical Management. Peter has held various local, regional and national clinical leadership roles including at the Ministry of Health. Since 2019 Peter has held the post of Chief Medical Officer at CMH - alongside this role Peter was appointed Deputy CEO in 2021.



**Fepulea'i**

**Margie Apa**

CEO - Counties Manukau Health

Fepulea'i is the current Chief Executive Officer for Counties Manukau Health (CMH). Fepulea'i's career has spanned twenty years in the public sector in Wellington and Auckland, including past roles at the Ministry of Health, the Health Funding Authority, Capital & Coast DHB, the Labour Market Policy Group (Department of Labour) and the State Services Commission. She has experience with strategic planning and programme management, Maaori and Pacific Health, organisational Communication and Human Resources.



**Kevin**

**Wightman**

Independent Trustee

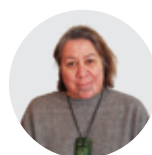
Originally from the UK Kevin has worked in Australia for over 20 years. He is passionate about improving the way clinical trials are delivered to better meet patients' needs. Kevin with more than 25 years' experience in leading Pharma, CRO, Site, and patient centric solutions providers across Asia Pacific, 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.



**Michael  
James**

Independent Trustee

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.



**Whetumarama  
Parore**

Ngāti Whātua, Ngāpuhi and Ngāti Kahu.  
Independent Trustee

Marama has worked in the New Zealand health sector for over 30 years including positions in the Central Regional Health Authority, Health Funding Authority and Plunket. She has been the General Manager, Maaori Health and Access & Optimal Use for PHARMAC and Pou Ahorangi, CEO for Te Rau Matatini, the National Maaori Mental Health and Addiction workforce and Director of Maaori Health in Healthcare NZ.

Marama is currently the Director Maaori Health for Kāhui Tuitui Tāngata – TAS and a member of Te Roopu – the Maaori Advisory Group for Health, Quality, Safety Commission.

## Senior Management Team

**Dr Edward Watson**

Chief Executive Officer

**Kate Msiska**

Business Manager

**Dr John Baker**

Clinical Director

**Alan Smith**

Information Systems Manager

**Anne Kendall**

Research Operations Manager

**Emani Setefano**

Company Accountant

# YEAR IN REVIEW

## From the CEO

**In 2021 Middlemore Clinical Trials celebrates 20 years of partnership with Middlemore Hospital. Set up as an independent trust in 2001 the Centre for Clinical Research and effective practice (CCRep) as it was known was designed to have a clear focus on clinical trials but still work closely with the physicians and nurses of Middlemore Hospital.**

Much has been achieved in those twenty years and the unit has matured both in terms of its understanding of and its ability to perform world class clinical trials for the benefit of the staff at Middlemore and the community of Counties Manukau.

This year has possibly been one of the most challenging for the unit as New Zealand continues its strategy of elimination of the COVID-19 virus. The ongoing global pandemic has continued to affect our supply chains and planning for clinical trials as our global partners themselves react to the demands of a new normal while dealing with the devastating health and economic effects of the virus in their own countries.

For MMCT this meant uncertainty or cancelled or delayed trial start dates and IP and laboratory kit supply disruption.

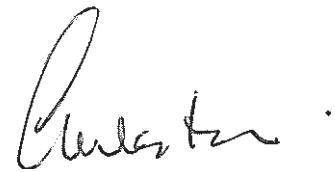
Through the beginning of 2021 we began to see the renewal of our sponsors desire to restart their trial pipelines. Our trial staff therefore had to meet the challenge of pivoting from uncertain global times to starting more trials in a compressed amount of time than ever before. In order to do so they had to balance maintaining quality and meeting the expectations of sponsors wanting their trials restarted or started as soon as possible.

For some staff the global pandemic meant a change of focus and a redefinition of goals. Thus in the first six months of 2021 we welcomed to the unit a group of highly talented new staff, both research nurses and university trained scientists, to help manage the increasing trial workflow. Our senior management also evolved as we welcomed Anne Kendall as the new Research Operations Manager and Emani Setefano as the Company Financial Accountant.

Indeed the first half of 2021 has been extremely busy for all staff. Their dedication, resilience and ability to cope with multiple conflicting demands meant that their task completion rate was higher than ever as they recruited a record number of new participants to the blossoming trial portfolio. For their professionalism and collective teamwork I am most grateful and thankful for.

During the year we also introduced and partnered with a growing number of new researchers and investigators. Our special thanks to the core group of physicians whose expertise and knowledge provide the strong back bone to the unit's trial pipeline. Specifically thanks to Dr John Baker, Dr Ian Rosen, Dr Renate Koops and Dr Joanna Wojciechowska.

As we move out of yet another community lock down the 20th year of operations for Middlemore Clinical Trials promises to be a busy and productive one both for our commercial and grant portfolios, our researchers and the community of Counties Manukau.



**Dr Edward Watson**

CEO



20<sup>th</sup>

anniversary





# GENERAL PERFORMANCE

Dashboard FY21

## MMCT Staff

### Total Staff

Total staff including Contractors who worked at MMCT during FY21

41

### Research Staff

Includes Nurses, Clinical Trial Coordinators, Phlebotomist & Pharmacist

31

### Commercial Trials

Total number of Commercial trials underway in FY21

65

### Grant Funded Trials

Total number of Grant funded /Investigator led trials

56

## Trial Metrics

### New Trial Activations

Commercial Trials activated during FY21

22

### Commercial Feasibilities

Total feasibilities received during FY21

182

### New Trial Participants

New entries into trials FY21

156

### Total Participants

Includes ongoing multi-year trials

391

## Our Revenues

### Total Revenue

\$5.16m

### Reserves

\$5.85m

### Grant Revenues

Designated/Restricted Reserves Spent During the year

\$1.12m

### Reserves Spent

Designated/Restricted Reserves Spent During the year

8%



## Hospital Activity

### Active Departments

Number of Hospital Departments we worked with in FY21

25

### Active Investigators

Number of Principal Investigators involved in Commercial trials in FY21

59

## Commercial Trials by Department

Top 12 Performers

## Trial Activity

Haematology

16

Gastroenterology

5

Rheumatology

9

Diabetes

8

Cardiology

5

Respiratory

2

Interventional Radiology

2

Renal

2

Clinical Lipidology

2

Orthopaedic

2

Vaccinology

3

Radiology

2

## Outpatient Activity

### Outpatient Visits

Total outpatient visits during the course of trials

2811

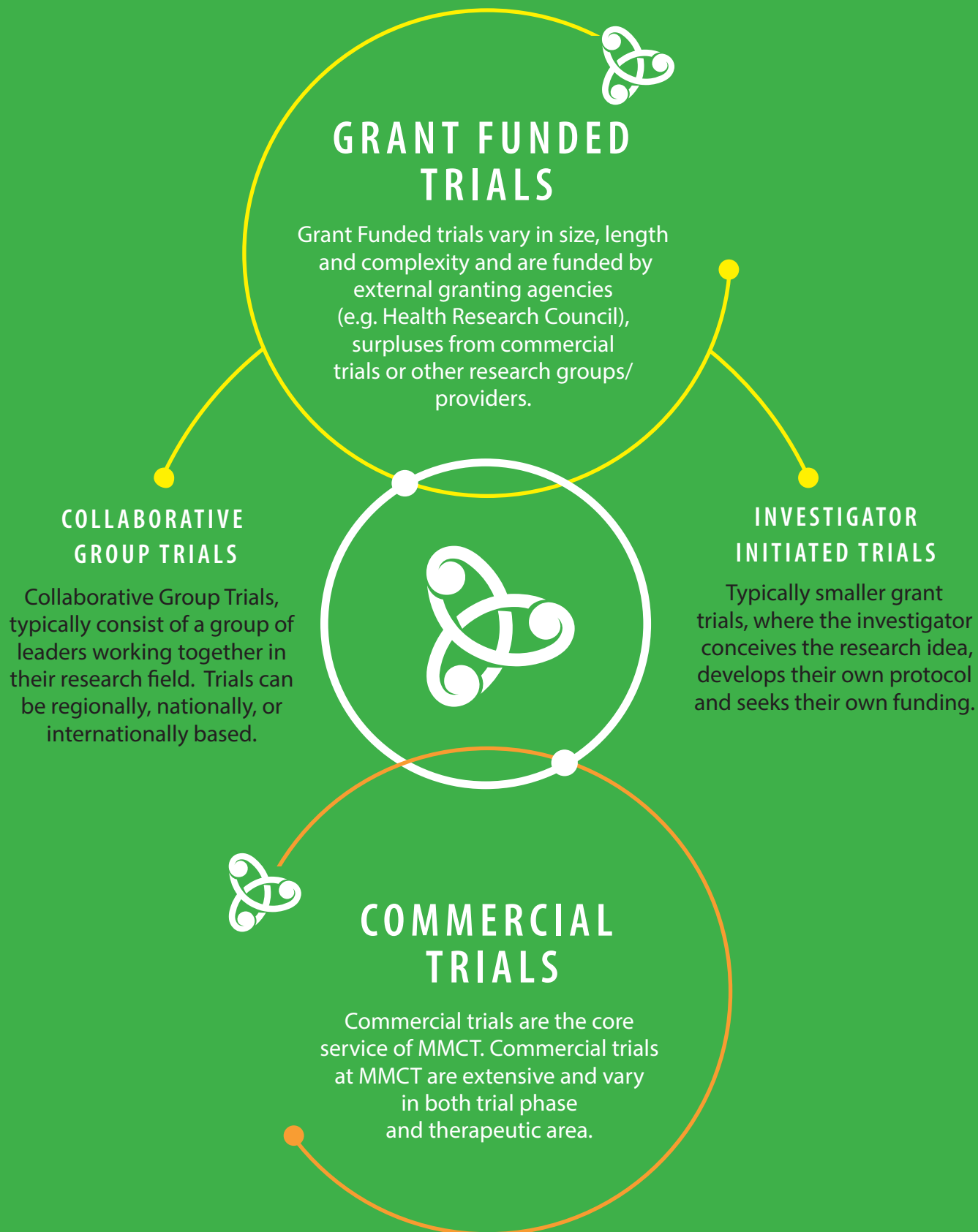
### Money Saved

Estimated Money saved by Service Outpatient Visits

\$850K

## WHAT WE DO

The main types of research we undertake



# WHY WE DO WHAT WE DO

At MMCT we believe we can promote 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 believe we can help change this through fostering deep partnerships in our community, among our people. We can help answer those questions that create doubt and promote the benefits of research thereby sowing the seeds of confidence in medicines and research that will not only help today's patients but future generations.

Such a plan involves partnerships with some of the most innovative companies on the planet whose vast resources are focused on finding treatments for today's diseases. Like us they believe that better health outcomes are achieved through strong relationships and cutting edge research.

Daily we convince such companies that New Zealand offers them a highly trained research workforce, steeped in experience which has the passion to reach out to the community and engage with them to produce high quality research outcomes.

Speed, Quality  
and Trust;  
it drives us.



## WHAT WE DO

### Commercial Clinical Trials

MMCT is a specialist research unit with specialist research staff. Research is the only discipline we do.

Similarly to last year we again increased our recruitment to target across all therapeutic areas. This illustrates our drive to improve and deliver outcomes that really matter. Additionally our continued production of high quality research data means that the investment sponsors have made in us is rewarded.

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 ensures that the First Patient In happens on time.

Adherence of our participants to completing the clinical trial they are involved in is also another aspect that we pride ourselves in. Our strong relationships with our participants means that they understand the benefits of taking part in a clinical trial both for themselves and future generations.

### Our Strengths

- Partnership with leading clinicians across 25 specialist departments
- Well trained, experienced and dedicated research staff who work within the GCP based guidelines and Standard Operating Procedures of our unit.
- Access to motivated participants within our diverse community including :
  - Strong partnerships with Middlemore Hospital and the local Primary Care Organisations
  - Sophisticated social media and advertising platforms
- Ability to ensure recruitment to agreed Targets
- Generation of high-quality data for our global partners with:
  - Paperless regulatory and participant files
  - Ability to provide remote monitoring access 24/7
- Speed of trial set up. Our staff manage the clinical trials process to ensure:
  - Smooth transition through Institutional Review Board (IRB)/Independent Ethics Committee (IEC) processes
  - Contracting specialists to ensure timely agreement in budget negotiations
  - Internal dedicated pharmacy and laboratory services ensures fast, efficient preparation for trial start
- MMCT has the facilities and expertise to undertake all Phases (I-IV) of clinical trials

## In FY21 MMCT managed 65 Commercial trials.

These included a mixture of Phase I to Phase III including both pharmaceutical and medical devices. Our infusion unit ensures that any early Phase trial is performed to the highest safety standards and undistracted from the service requirements of our surrounding large hospital.

As always we performed many of the major medical discipline trials particularly in the areas of malignant haematology, hepatology, metabolic disease, viral infectious diseases and chronic illnesses that are prevalent in our community.

Increasingly we are performing more device trials with our motivated surgical colleagues in orthopaedics, plastics and general surgery.

## FY21 MMCT Commercial Trials Overview

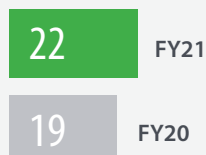
### Active Commercial Trials



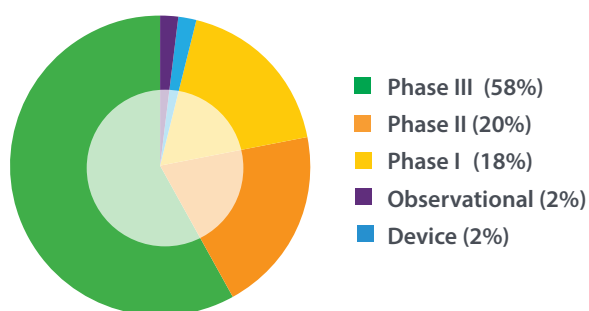
### New Recruiting Trials



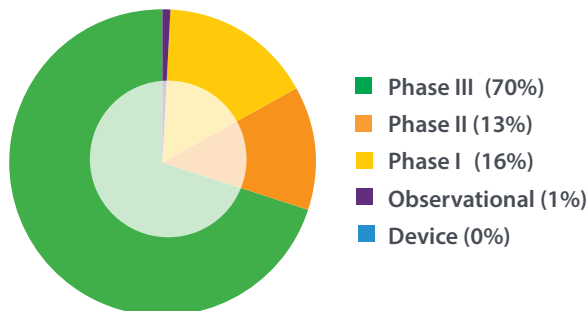
### New Trials Activated



## FY21 Commercial Trials by Study Phase



## FY20 Commercial Trials by Study Phase



# WHAT WE DO

## Commercial Clinical Trials

### Top Recruiting Departments at CM Health in FY21

Commercial Trials FY21 by Department	Number of Trials	Number of Participants
HAEMATOLOGY	16	34
RHEUMATOLOGY	9	34
HEPATOLOGY	8	33
DIABETES	6	55
CARDIOLOGY	5	34
GASTROENTEROLOGY	5	21
VACCINOLOGY	3	43
RESPIRATORY	2	3
RADIOLOGY	2	5
CLINICAL LIPIDOLOGY	2	12
RENAL	2	33
ORTHOPAEDICS	2	12
DERMATOLOGY	1	5
PAEDIATRICS	1	3
PLASTICS	1	6
<b>Grand Total</b>	<b>77</b>	<b>333</b>

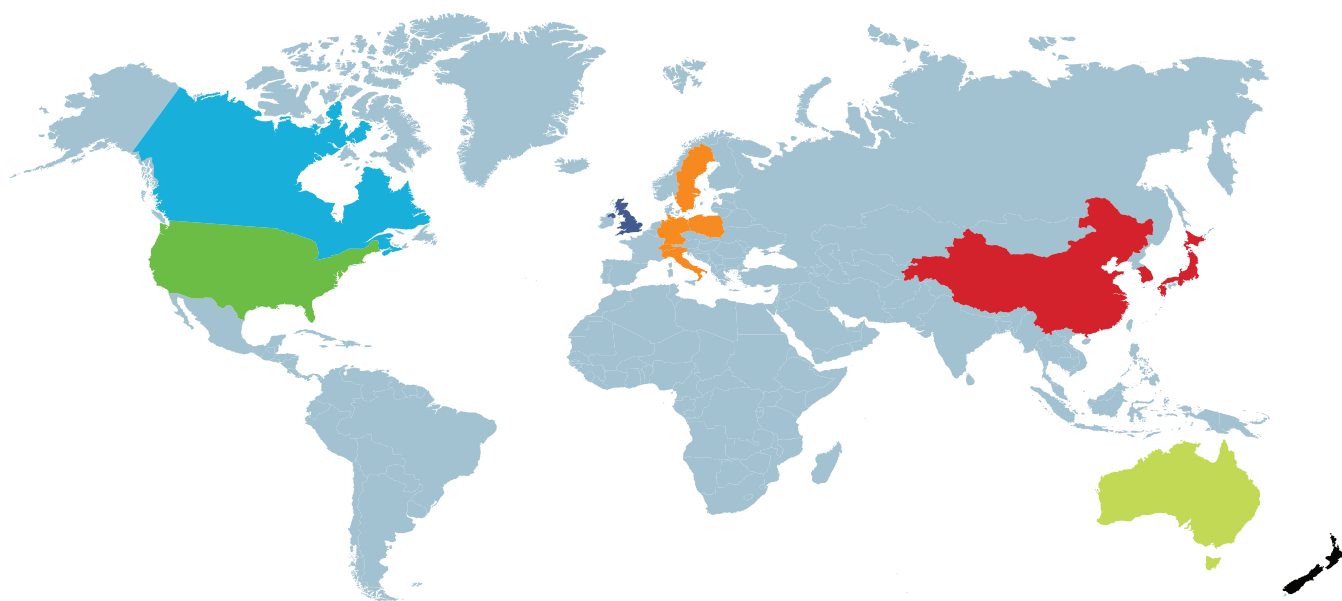
### Clinical Trial Recruitment Performance FY21

122%

Overall percentage of  
participants recruited to target  
for trials with enrollment  
ending in FY21

53%

of active trials in  
FY21 exceeded  
recruitment target



### Domiciliary origin of Sponsors that MMCT worked with in FY21

- United States (42)
- Australia (3)
- Canada (3)
- China (3)
- Germany (2)
- Japan (2)
- New Zealand (1)
- Poland (1)
- South Korea (1)
- Sweden (1)
- Switzerland (2)
- United Kingdom (2)





# WHAT WE DO

## Grant Funded Research

The Grant Research portfolio consists of trials that are initiated by investigators within the hospital, collaborative research groups from around the world, or industry in response to a need within the community we serve.

Grant research is performed by Principal Investigators from many different clinical backgrounds including Clinicians, Nurses, Midwives, Physiotherapists, Occupational Therapists and Pharmacists. The Grant research team works in partnership with Counties Manukau Health to support grant funded research at Middlemore Hospital.

Over the last year, several Counties Manukau Health investigators were successful in their bids for grant funding resulting in public-good research trials. The following are examples of the breadth of work:

The Potter Masonic Trust awarded ophthalmologist, Dr Rasha Altaie, funding to pursue the use of **Artificial Intelligence to diagnose Keratoconus**. Keratoconus is a disease that alters the shape of the cornea leading to vision loss and in some cases, blindness. NZ has a high burden of this disease that disproportionately affects Māori and Pacific children and requires a highly experienced specialist to diagnose the condition. As early detection is key to preventing the devastating effects of keratoconus, this project has used thousands

of corneal images (healthy and diseased) to train an algorithm to identify keratoconus without the need for specialist input. The next step will be to carry out a prospective trial to compare the algorithm against the gold standard (diagnosis by corneal specialists). Over a 3-month period, 1000 patients that require an eye assessment (including suspected keratoconus) will be screened at the Manukau Super Clinic by both the algorithm and a specialist. At the conclusion of this, the investigators expect the algorithm to achieve >90% specificity. Technology such as this can drastically shift healthcare as it would allow for the rapid and inexpensive detection of conditions like this in community-based eye care settings.

**The OSCAR trial – Optimising Selenium status to prevent Colorectal Adenoma Recurrence** – was conceived by Dr Michael Jameson from the Waikato Clinical School (University of Auckland) and has been awarded funding by the Centre for Cancer Research. OSCAR is the first Oncology grant trial that Middlemore Clinical Trials has supported and represents collaboration between the Waikato Clinical School, the University of Auckland, and Middlemore Hospital. Dr Maree Weston is the lead investigator at Middlemore. OSCAR is a Phase 1B study that aims to determine whether selenium can reduce the recurrence of advanced colorectal adenoma (bowel cancer) in the New Zealand population. Bowel cancer is the third most common cancer in NZ and its occurrence is correlated with low intake of selenium. Selenium plays a critical role in cancer prevention and the study aims to optimise the dose of selenium that could potentially reduce the recurrence of this type of cancer. This trial will recruit 60

participants with advanced colorectal cancer across Middlemore and Waikato hospitals. The results of the study will be used to inform the design and feasibility of a phase 3 randomised, placebo-controlled trial to evaluate the ability of selenium to reduce recurrence of advanced adenomas.

**FRAIL-M – Frailty-stratified, randomised controlled Bayesian adaptive trial of bortezomib versus lenalidomide in transplant-ineligible myeloma** – is a collaborative group study partially funded by the Australian Leukaemia and Lymphoma Group (ALLG). Recent randomised controlled trials have identified lenalidomide and bortezomib as the most effective therapies for treatment of multiple myeloma, however, there is no definitive guidance on how these medications should be administered in newly diagnosed transplant-ineligible patients. The aim of the study is to identify the optimal dosages of both lenalidomide and/or bortezomib, and to assess whether either one is superior to the other. Participants will be randomised to a treatment arm based on their frailty assessment which is expected to increase the likelihood they will complete the intended course of treatment. This collaborative group study is valuable because bortezomib and lenalidomide have never been compared head-to-head in clinical trials as there has been no commercial incentive to do so. FRAIL-M New Zealand is led by haematologist, Dr Rajeev Rajagopal and the Haematology Department at Middlemore Hospital, with trial coordination support provided by Middlemore Clinical Trials Research Nurses and Clinical Trial Coordinators. This study will be open for 48 months and has a recruitment target of 10 patients.

### Notable studies currently recruiting at Middlemore Hospital include:

Aptly named after the US company that funded this work, **FluLab – influenza in a post-COVID** world is a study that was initiated this winter. Locally led by paediatric consultants, Dr Adrian Trenholme and Dr Catherine Byrnes, FluLab is a collaborative project with The University of Auckland and the Institute of Environmental Science and Research. Non-pharmaceutical interventions such as border closures, social distancing and lockdown restrictions prevented the development of natural seasonal immunity to respiratory viruses resulting in the recent RSV epidemic in children. Much like that, this work expects to detect resurgence of multiple respiratory illnesses, particularly influenza, once COVID-19 restrictions ease.

South Auckland is the focus of this research due to the social deprivation that exacerbates disease spread in this community, and proximity to the international airport that acts as a vector for disease transmission. Over a two-year period, thousands of swabs will be taken from children with cold and flu symptoms at early childhood centres, GP practices and Middlemore hospital to establish how a year of minimal exposure to respiratory viruses has affected subsequent transmission of disease in preschool aged children. Further to this, families of these children will be invited to participate in focus group interviews to determine the social and economic impact of respiratory illnesses on whaanau and communities.

### ASCOT – the AustralaSian COVID-19

**Trial**, is a multi-centre randomised adaptive platform clinical trial to assess clinical, virological, and immunological outcomes in patients with SARS-CoV-2 infection

### FY21 Grant funded trials - by department

Hospital Department	Initiated at CM Health	Initiated Elsewhere	Total Grant funded trials
ALLIED HEALTH	-	2	2
CARDIOLOGY	-	4	4
DIABETES	1	-	1
GASTROENTEROLOGY	1	1	2
EMERGENCY DEPARTMENT	-	3	3
HAEMATOLOGY	-	9	9
HOME HEALTH	-	1	1
INFECTIOUS DISEASES	2	-	2
INTENSIVE CARE UNIT	-	8	8
NEONATAL	-	2	2
ONCOLOGY	-	1	1
OPHTHALMOLOGY	1	1	2
PAEDIATRICS	1	7	8
PLASTICS	2	-	2
RENAL	1	2	3
RESPIRATORY	1	3	4
SURGERY	1	-	1
WOMENS HEALTH	-	1	1
<b>Total</b>	<b>12</b>	<b>44</b>	<b>56</b>

(COVID-19). The overall sponsor of the study is the University of Melbourne, but the New Zealand arm of the study is funded by the Health Research Council, and led by clinical microbiologist and infectious disease consultant, Dr Susan Morpeth. The adaptive platform design allows investigators to test a variety of potential treatments for people admitted to hospital with COVID-19 but are well enough to not require intensive care. It offers greater flexibility than a traditional fixed clinical trial design as it uses outcome data as it is accumulated to modify the course of the trial. This trial design is highly relevant as the COVID-19 pandemic continues to evolve.

The ASCOT ADAPT protocol has 3 treatment domains: antiviral, antibody and anticoagulation. Participants can be randomised to more than one domain if they meet eligibility criteria. Participation in ASCOT is open to adults with COVID-19 that have been hospitalized within 14 days of symptom onset. Notably, pregnant women are eligible to participate in both the antibody and anticoagulation domains. ASCOT is actively recruiting at 29 sites across New Zealand, Australia, and India. To date, across all sites, 916 individuals have been enrolled in this trial. There are currently seven hospitals participating in New Zealand.

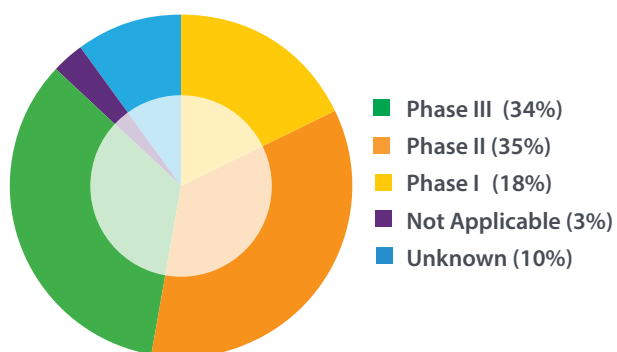
# FEASIBILITIES

## MMCT performance on new trials

### New Trial Feasibilities Received in FY21

Therapeutic Area	Phase I	Phase I/II	Phase II	Phase II/III	Phase III	Phase Unknown	Phase n/a	Total
Cardiology				2	4	1		7
Chemical Pathology				2				2
Clinical Lipidology			1	2				3
Dermatology	2		3	4		2		11
Diabetes		1		3	2	2		8
Emergency Department						1		1
Gastroenterology				4	1	2		7
Haematology	5	3	5		19	1		33
Hepatology	5	3	10	1		3		22
Infectious Disease		1	1		1	2	2	7
Intensive Care			1					1
Mental Health						1		1
Neonatal					1			1
Neurology	2		2		4	2	1	11
Oncology	4	1			2	1		8
Ophthalmology					1			1
Orthopaedics	3							3
Otorhinolaryngology (ENT)					1			1
Paediatrics			4		4	1	1	10
Renal			1		6			7
Respiratory	2		4	1	7	1		15
Rheumatology			7		3			10
Surgery			1					1
Urology					1			1
Vaccinology	2		1	1	3	1		8
Womens Health				1		1		2
Grand total	25	9	41	21	60	22	4	182

### 182 Total Feasibilities Received in FY21



### Clinical Trial New Feasibilities Received



# FEASIBILITIES

## Engagement during FY21

65 different sponsors and 21 different CRO's engaged with MMCT during FY21

Sponsors FY21		CROs FY21
AbbVie Inc	HUYA Bioscience International	Accelagen
Acceleron	IMV Inc	Bayer New Zealand
Alnylam Pharmaceuticals	Incyte	Clinipace
Arbutus Biopharma	Insmed	CliniTrials
ARCUS	Iveric Bio	Covance
Armata Pharma	Janssen-Cilag Pty Ltd	DAVA Oncology
Arrowhead Research	KoBioLabs	EganLee
Assembly Biosciences	Loxo Oncology	ICON Clinical Research New Zealand
AstraZeneca AB	Medical Developments International	IQVIA (Quintiles)
Bausch Health	Mei Pharma	Medpace
Bayer HealthCare AG	Merck	Molecule2Market
BeiGene	Mirum Pharmaceuticals	Novotech
BioAge Labs	ModernaTx, Inc.	PAREXEL International
Biogen	Molecular Templates	Pharmaceutical Solution Ltd
Boehringer Ingelheim GmbH	Neuren Pharmaceuticals Ltd	PPD
Cerecin Australia	Novaremed	PRA International
Chinook Therapeutics	Novavax	Premier Research Australia
Clover Biopharmaceuticals	Otsuka Pharmaceutical Co Ltd	PSI-CRO
Dynavax Technologies	Parexel	Southern Star Research
Eidos Therapeutics	Persica Pharmaceuticals Ltd	Syneos Health
Endeavour Biomedicines	Pfizer Inc	
EpimAb Biotherapeutics	Pleiogenix	
Evelo Biosciences	Roche	
FibroGen, Inc.	Ryvü Therapeutics	
Finch Therapeutics	Shionogi & Co	
Fisher & Paykel Healthcare	Sierra Oncology	
Genentech	SpineThera	
Geneos Therapeutics	Unity Biotechnology	
Gilead	V-Check	
GlaxoSmithKline	Venatorx Pharmaceuticals, Inc	
GW Research Ltd	VIR Biotechnology	
H. Lundbeck		
Horizon Therapeutics		

65  
unique sponsors  
requested trial  
feasibilities  
in FY21

# BENEFITS

## To the community of research

**Of the participants who have taken part in a clinical trial run by MMCT, 99% said they would take part in another or recommend that family and friends did.**

Factors that are known to influence such a positive participation experience in a clinical trial include:

### Personalisation of care

Often in a busy hospital or GP clinic patients can feel less connected with their carers. In a clinical trial, time is not the focus but building a relationship with specialist nurses and doctors. 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<sup>1</sup> performed at Middlemore Hospital, patients on interventional diabetic and cardiovascular clinical trials had a 55% overall reduction in death over the 3 years studied. Furthermore, the study showed 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 tight regulatory policies in place to restrict the use of novel medications until they are proven to be safe. This can often mean that 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 charge (as does the government).

### Constant drive for greater knowledge

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.

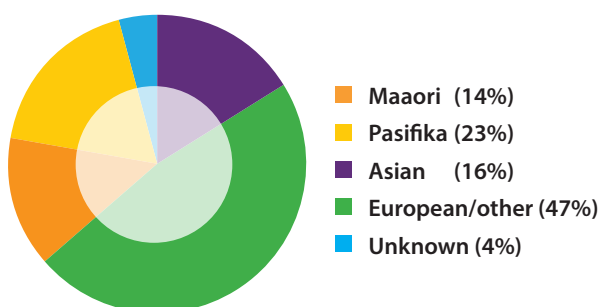
### Addressing health inequity

Health inequity is linked to economic factors, social deprivation and access to care. A significant number of our community in Counties Manukau have poorer outcomes than other parts of the country. This is particularly important for the Pasifika and Maaori communities in Counties Manukau. Clinical trials can provide access to novel treatments years in advance, combined with producing better health outcomes for participants. These factors can help address some of the barriers to better care.

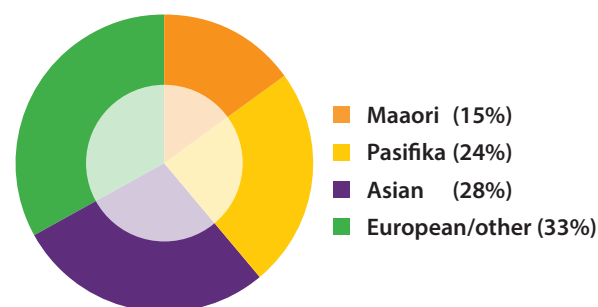
<sup>1</sup> Baker, J. R., Vandal, A. C., Yeoh, J., Zeng, I., Wong, S., & Ryan, S. N. (2013). Clinical trial participation improves outcome: A matched historical cohort study. *Clinical Trials*, 10(5), 735–743. <https://doi.org/10.1177/1740774513496915>

Clinical trials are spread across main ethnic groups in the local community

**FY21 ethnicity mix of Trial Participants**



**2020 ethnicity mix of the CM Health local community**



# BENEFITS

## For the Hospital and District Health Board (DHB)

**MMCT's unique operating model for New Zealand as an independent trust performing research on behalf of a major hospital has both tangible and intangible benefits.**

**These include:**

### **We are experts at managing research**

Research is all we do. This means easier engagement and opportunities for hospital based staff to be involved and the likelihood of clinical trials optimizing recruitment. Being the central point of contact for all therapeutic areas makes for deeper and broader relationships with sponsors with standardization of the feasibility review, contracting and budget negotiation process.

### **Funding made available for more research**

Being a charitable trust with no shareholders means the retained earnings are channeled back to help support increasing the capacity and capability for departments to perform more research. This may mean for example: 'buying out' research time for doctors, nurses or allied health professionals or providing

for non-standard of care procedures on investigator initiated or collaborative group trials. This allows research to flourish and grow within the hospital.

### **Full cost recovery**

We have the ability to separate the cost of performing research from the activities of standard of care that the hospital normally provides. Often in the DHB clinical trial model such costs are difficult to untangle meaning that service departments within public hospitals unwittingly subsidize research by bearing the cost of staff and even treatments.

### **Economies of scale**

Providing central management of clinical trials for all departments within the hospital mean that the supportive functions such as finance, contract negotiation, HR, marketing are centralized and efficiencies can be shared across all departments and all Phases of research.

### **Potential cost savings to the DHB**

- In an average year over one million dollars is saved by the DHB by patients attending outpatient visits as part of clinical trials and hence not having to attend hospital service outpatient visits.
- In 2019 it was estimated that the haematological department alone saved over \$750,000 in medication costs for those patients with malignant disease receiving their medication as part of a clinical trial. This is thought to have increased year on year as the haematological department embarks on even more trials.

### **Attraction of top staff**

- Hospital departments that have a strong research culture appear to attract and have the choice of excellent top class clinical staff who want and consider research to be part of what their job entails.
- Clinicians who are involved in research often evolve their practice of medicine more quickly than those not involved in research. This is a result of working with cutting edge technology, innovation and collaborations from around the world that challenges the current dogma of patient care.

### **Foster engagement with Research Organisations**

Research is a significant channel of engagement with leading Universities both locally and globally. Research is a major pillar of what Universities do. Being engaged in research means hospitals can form stronger relationships with such institutions based on mutually aligned goals and benefits.

### Leeone P.

*Leeone has Chronic Lymphocytic Leukaemia*

#### **How was your quality of life affected by the disease?**

I had CLL for 20 years and my life was not affected at all. However, as the disease progressed further I needed treatment.

#### **How did you hear about taking part in Clinical Research?**

I was informed by Dr Sharon Jackson that I needed to start having treatment and she told me about the trials. She gave me all the information to read, about the trials drugs, and I basically had 24 hours to make a decision as pre-trials test needed to be done.

#### **Can you tell me about your experiences of being part of Clinical Research?**

I was very nervous about being part of the drug trials, but to be honest, the thought of chemotherapy scared me even more.

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

I would definitely recommend to be part of drug trials. It gave me an opportunity to be part of something that could, one day, help others with such a horrible disease, to get better treatment, than what is on offer in today's world.



### Thomas S.

*Tom has diabetes*

#### **How was your quality of life affected by the disease?**

My life didn't slow down and I am trying to live day by day as I can. I do what I want to do and don't let the disease interfere with my daily life.

#### **How did you hear about taking part in Clinical Research?**

I was sent a text and asked if I wanted to participate in the trial from an employee of MMCT.

#### **Can you tell me about your experiences of being part of Clinical Research?**

I felt as if I was there to help the next generation. I also felt that everyone I encountered whilst involved in the clinical trial was respectful towards me and worked hard to make sure I was heard.

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

Yes very much so.

### Ray K.

*Ray has Chronic Lymphocytic Leukaemia*

#### **How was your quality of life affected by the disease?**

When first diagnosed with the disease my quality of life was not affected, other than nose bleeds, as it was in its early stages.

Looking back other issues I experienced at the time, such as tiredness, I blamed on getting old. Now, being in remission, I am not getting as tired as before.

#### **How did you hear about taking part in Clinical Research?**

I heard about the trial when the blood results indicated that I needed to start treatment. At a meeting at the hospital, I was told about the trial of new drugs to treat the condition and asked if I would like to apply to join the trial.

#### **Can you tell me about your experiences of being part of Clinical Research?**

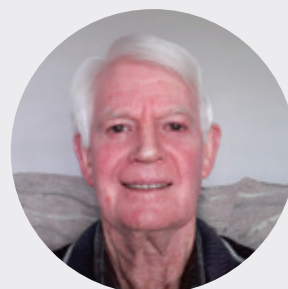
I have nothing but the highest praise for all the staff I met at MMCT and am grateful for the work they did. It is pleasing to be currently in remission.

I have been able to continue my life including sports as normal during the trial, apart from the brief time of hospital visits and when under lockdown due to COVID-19.

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

I highly recommend anyone to consider being part of a trial run by Middlemore Clinical Trials.

For me the new treatment of my condition was far less unpleasant than if I had the usual treatment.

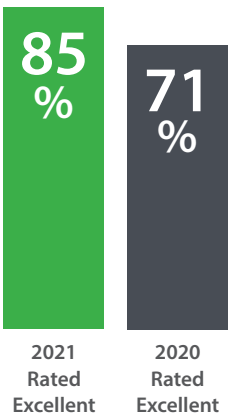




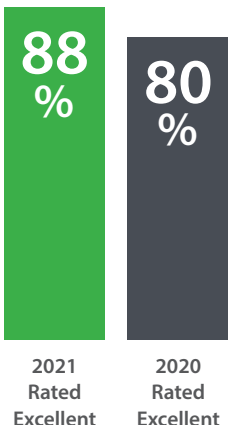
# PARTICIPANT INSIGHTS

## Surveys

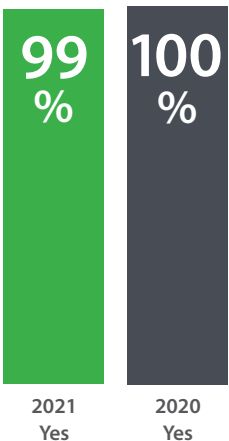
Rate your overall experience in being involved in a clinical trial



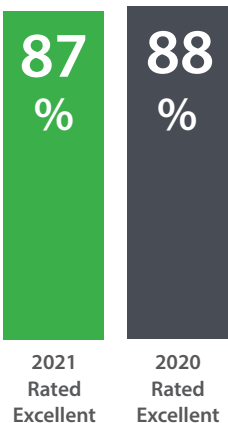
Rate your overall satisfaction with MMCT



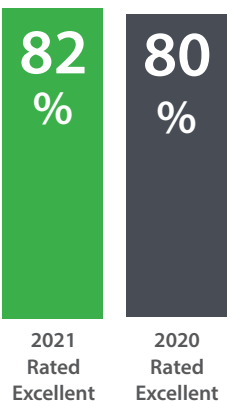
Would you recommend being involved in clinical research to others?



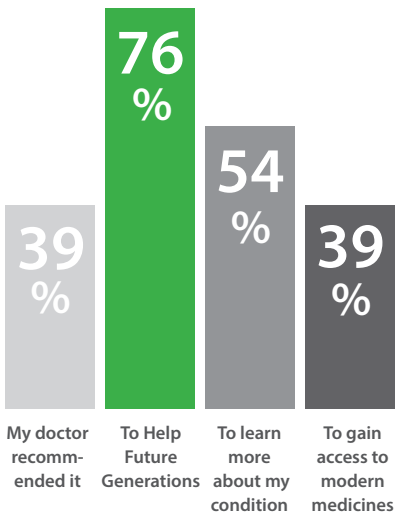
Rate the friendliness of our staff to you and your whanau



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



2021 - What is the reason you took part in a clinical trial?



# MMCT AWARDS 2021

## The MMCT Award Recipient 2021

### **Lauren Fernyhough**

Research Team Leader - Recruitment

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

## Certificate of Excellence

### **Catherine Howie**

Senior Regulatory Specialist

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

## Certificate of Excellence

### **Mary Paul**

Research Nurse

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



Left to right - Lauren Fernyhough, Catherine Howie, Mary Paul.

# UPCOMING DEPARTMENTS

## OPHTHALMOLOGY

### Clinical Lead: Dr Graham Reeves

Dr Rasha Al Taie was successful in receiving funding from the Potters Masonic Trust to investigate the early detection of keratoconus using artificial intelligence. This condition disproportionately affects adolescent individuals of Maaori and Pacific Island decent, the aim of this study is to prevent kids from losing vision in New Zealand.

We look forward to working with the Ophthalmology department in the future.

## PLASTICS SURGERY

### Clinical Lead: Dr Michelle Locke

The department is involved in a trial looking at the use of Negative Pressure Wound Therapy (NPWT) System for the management of closed surgical wounds.

### MMCT

Mary Paul (Research Nurse) and Jamie Duckworth (Research Nurse).

## INFECTIOUS DISEASE

### Clinical Lead: Dr Chris Luey

Dr Susan Morpeth and Dr Genevieve Walls were both awarded substantial Health Research Council grants to carry out their respective trials using adaptive platforms. ASCOT, led by Dr Morpeth randomises COVID-19 patients into potential treatment options for individuals admitted to the hospital but do not require intensive care. Dr Walls leads the SNAP study in New Zealand that, much like ASCOT, aims to identify the effect of a range of clinical interventions on all-cause 90-day mortality of a *Staphylococcus aureus* bloodstream infection. Both ASCOT and SNAP are being conducted in New Zealand and Australia and have the possibility to re-purpose existing treatments for these highly infectious diseases.

### MMCT

Dana de Krester (SNAP NZ Project Manager), Dr Nicola Jackson (Senior Regulatory and Grants Associate)

### CM Health:

Dr Susan Morpeth (Investigator),  
Dr Genevieve Walls (Investigator),  
Dr Christopher Hopkins (Sub-investigator),  
Dr Christopher Luey (Sub-investigator),  
Dr Stephen McBride (Sub-investigator), and  
Dr David Holland (Sub-investigator).

## ADULT REHABILITATION & HEALTH OF OLDER PEOPLE (ARHOP)

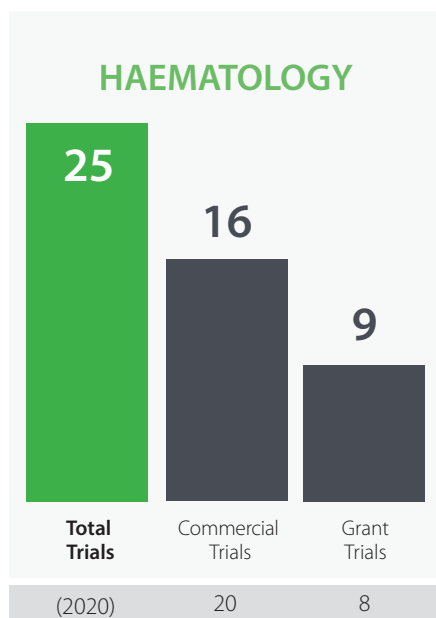
### Clinical Lead: Dr Sunita Paul and Dr Julie Beck

ARHOP is excited to be involved in research, particularly pertaining to disability, stroke, spinal injury, and rehabilitation in older people. This includes research into vaccines against disease such as Respiratory Syncytial Virus (RSV), which can be very impactful in older people.

We look forward to growing our collaboration with ARHOP to contribute to research in this population.

# AREAS OF RESEARCH

## Activity by department in FY21



## HAEMATOLOGY

### Clinical Lead: Dr Sharon Jackson

Haematology research had a very busy year receiving the most feasibilities of any department and performing the most clinical trials. The department continues to maintain an active research program with a combination of both commercial and grant-funded trials. Many of these Phase II and III trials provide patients with access to medicines that are otherwise not available in New Zealand, or not available for the condition under investigation. There have been some changes in the Departments Haematologists as Dr Hilary Blacklock retired during the year following her impressive career both as a clinician and a researcher. The department welcomed Dr Kirsty Marshall to the SMO team, Dr Marshall comes with a strong interest in research.

### RESEARCH TEAMS

#### MMCT

Nicola Jackson (Senior Grants & Regulatory Associate),  
 Alice Cassidy (Research Nurse),  
 Anne Kendall (Research Operations Manager),  
 Emma Dorsey (Clinical Trial Coordinator),  
 Ella Liang (Research Nurse),  
 Katie Seto (Research Nurse),  
 Liz Walker (Research Nurse),  
 Sharlyn Benemerito (Research Nurse),  
 Rebecca McMillan (Clinical Trial Coordinator).

#### CM Health

Dr Samar Issa (Investigator),  
 Dr Sharon Jackson (Investigator),  
 Dr James Liang (Investigator),  
 Dr Rajeev Rajagopal (Investigator),  
 Dr Gordon Royle (Investigator),  
 Dr Kirsty Marshall (Investigator).

This department predominantly engages in research related to respiratory illnesses and conditions that are disproportionately prevalent in children within the local community. Some of these include: bronchiolitis, bronchiectasis, influenza and acute rheumatic fever.

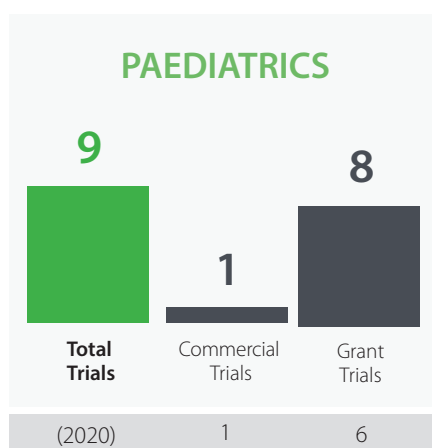
### RESEARCH TEAMS

#### MMCT

Renee Railton (Research Manager – Grants),  
 Dharshini Sreenivasan (Business Associate – Grants),  
 Rebecca McMillan (Clinical Trial Coordinator),  
 Lisa Chang (Pharmacist),  
 Anne Kendall (Research Operations Manager),  
 Dr Katy Young (Paediatric Registrar).

#### CM Health

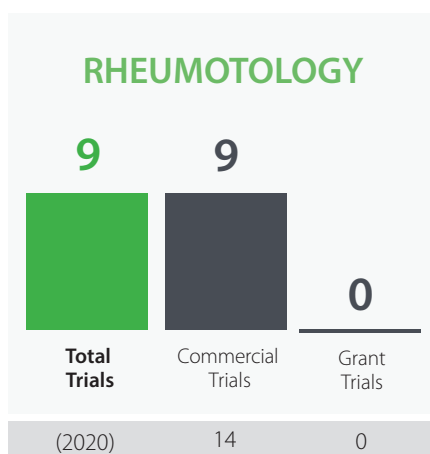
Dr Christine McIntosh (Investigator),  
 Dr Tim Hill (Investigator)  
 Dr Mike Meyer (Investigator),  
 Dr Jocelyn Neutze (Investigator),  
 Dr Adrian Trenholme (Investigator),  
 Dr Rachel Webb (Investigator),  
 Dr Alana Ainsworth (Research Fellow),  
 Dr Shanthi Ameratunga (Investigator),  
 Dr Zahra Al-Khudairi (Research Fellow),  
 Renee Clark (Research Nurse),  
 Shirley Lawrence (Research Charge Nurse),  
 Maricar Santiago Maminta (Research Nurse),  
 Mandy Retter (Research Nurse),  
 April Hwang (Research Nurse),  
 Angela Watson (Research Nurse)  
 Kelly Rocznik (Research Nurse),  
 Gale Spense (Research Coordinator).



## PAEDIATRICS

### Clinical Lead: Dr Richard Matsas

The Paediatric and Neonatal teams have had another outstanding year in research. The department engaged in mostly grant funded trials and a commercial infant respiratory syncytial virus (RSV) trial.



## RHEUMATOLOGY

### Clinical Lead: Dr Sunil Kumar

The Rheumatology research portfolio is broad covering novel treatments for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, giant cell arteritis, gout and systemic lupus erythematosus. These trials often provide patients with access to medicines that are otherwise not available in New Zealand which can have a life changing impact on a participant's condition.

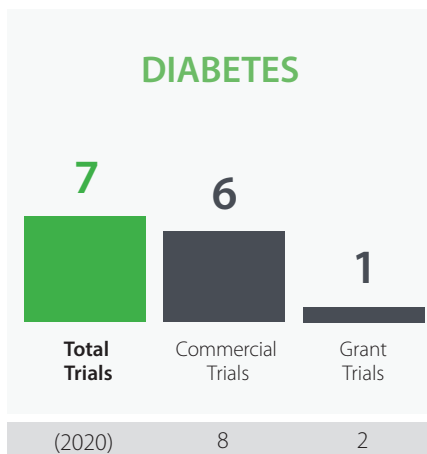
### RESEARCH TEAMS

#### MMCT

Catherine Howie (Senior Regulatory Specialist),  
Anne Kendall (Research Operations Manager),  
Mary Paul (Research Nurse),  
Clarence Vivar-Bicani (Research Nurse),  
Kieran Latto (Clinical Trials Coordinator).

#### CM Health

Dr Sunil Kumar (Investigator),  
Dr Mark Sapsford (Investigator),  
Dr Rajiv Gupta (Sub-Investigator).



## DIABETES

### Clinical Lead: Dr Brandon Orr Walker

The Diabetes team works closely with CM Health clinicians to undertake commercial and grant-funded clinical trials. A recent focus is the area of chronic kidney disease associated with Type 2 Diabetes Mellitus (T2DM) which is highly prevalent in our local community. Dr John Baker (Clinical Director of MMCT) is the lead investigator for all of the commercial diabetes trials and co-lead investigator on the grant funded trials.

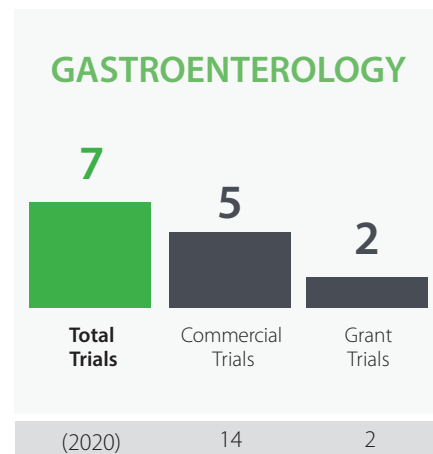
### RESEARCH TEAMS

#### MMCT

Dr John Baker (Investigator),  
Dr Renate Koops (Investigator),  
Dr Ian Rosen (Sub-Investigator),  
Dr Joanna Wojciechowska (Sub-investigator),  
Maryam Apat (Research Nurse),  
Sarah Baresic (Research Nurse),  
Jamie Duckworth (Research Nurse),  
Lauren Fernyhough (Research Nurse),  
Susan Ross-Heard (Research Midwife).

#### CM Health

Dr Brandon Orr-Walker (Investigator),  
Dr John Griffiths (Sub-Investigator),  
Dr Rinki Murphy (Sub-Investigator).



## GASTROENTEROLOGY

### Clinical Lead: Dr Anurag Sekra

The Gastroenterology Department continues to have a strong portfolio predominantly in commercial clinical trials over the past two years. A significant focus of the current research portfolio is finding a cure for Chronic Hepatitis B (led by Dr Tien Huey Lim) and NASH (Non-Alcoholic Steatohepatitis), with other research interests including ulcerative colitis and Crohn's disease (led by Dr Ashok Raj).

### RESEARCH TEAMS

#### MMCT

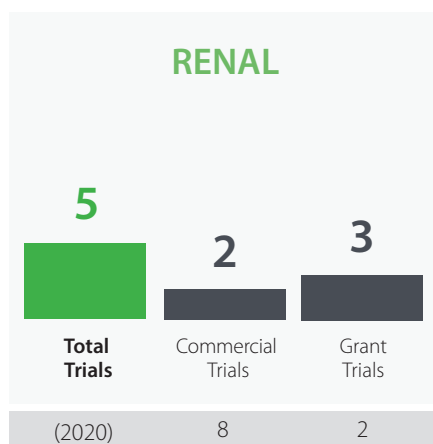
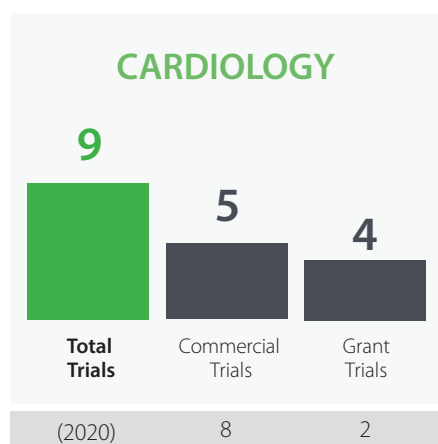
Dr John Baker (Sub-Investigator),  
Dr Renate Koops (Sub-Investigator),  
Dr Joanna Wojciechowska (Sub-investigator),  
Sarah Baresic (Research Nurse),  
Johanna Nightingale (Research Nurse),  
Kieran Latto (Clinical Trials Coordinator),  
Cyrene Sto Domingo (Research Nurse),  
Lisa Chang (Pharmacist).

#### CM Health

Dr Tien Huey Lim (Investigator),  
Dr Ashok Raj (Investigator),  
Dr Adele Melton (Sub-Investigator),  
Dr Sethu Nagappan (Sub-Investigator).

# AREAS OF RESEARCH

## Activity by department in FY21



## CARDIOLOGY

### Clinical Lead: Dr Selwyn Wong

Most consultants in the Cardiology department are involved in research, reflecting the department's strong research culture. The department has diverse research interests including chronic heart disease, heart failure, interventional cardiology procedures, chronic angina and coronary devices.

### RESEARCH TEAMS

#### MMCT

Alice Cassidy (Research Nurse),  
Kavita Gounder (Research Nurse),  
Mandy Ma (Research Nurse),  
Liz Walker (Research Nurse),  
Rebecca McMillan (Clinical Trials Coordinator).

#### CM Health

Dr Wil Harrison (Investigator),  
Dr Patrick Kay (Investigator),  
Dr Mayanna Lund (Investigator),  
Dr Douglas Scott (Investigator),  
Dr Tim Sutton (Investigator),  
Dr Selwyn Wong (Investigator),  
Dr Peter Barr (Sub-Investigator).

## RENAL

### Clinical Lead: Dr Jamie Kendrick-Jones

The department has a very inclusive research culture where most department clinicians are involved in research. The researchers engaged in grant and commercially-funded research in the areas of chronic and end stage kidney disease, IgA neuropathy and hypertension.

### RESEARCH TEAMS

#### MMCT

Dr John Baker (Sub-Investigator),  
Emma Dorsey (Clinical Trials Coordinator),  
Cyrene Sto Domingo (Research Nurse),  
Mary Paul (Research Nurse),  
Dana de Krester (Clinical Trials Coordinator),  
Johanna Nightingale (Research Nurse),  
Jamie Duckworth (Research Nurse).

#### CM Health

Dr Christopher Hood (Investigator),  
Dr Jamie Kendrick-Jones (Investigator),  
Dr Mark Marshall (Investigator),  
Dr Rachel Walker (Investigator),  
Dr Jonathan Hsiao (Sub-Investigator),  
Dr Hari Talreja (Investigator),  
Dr Xiang (Luke) Li (Sub-Investigator),  
Dr Kalpa Jayanatha (Investigator).

## ORTHOPAEDIC SERVICES AND THE AUCKLAND SPINAL REHABILITATION UNIT

### Clinical Lead: Dr Rodney Gordon

Mr Alpesh Patel and Mr Simon Manners are working on a trial looking at the effect of Air Surgical Humidification on wound temperature during spinal surgery and a negative pressure wound dressing study. Mr Alpesh Patel and Mr Simon Manners are also working on two commercial device trials one surgical and the other a negative pressure dressing.

### RESEARCH TEAMS

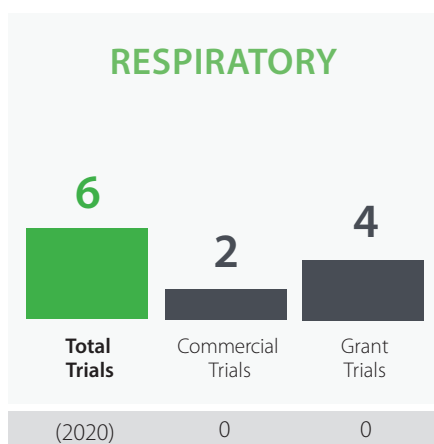
#### MMCT

Jamie Duckworth (Research Nurse),  
Mary Paul (Research Nurse).

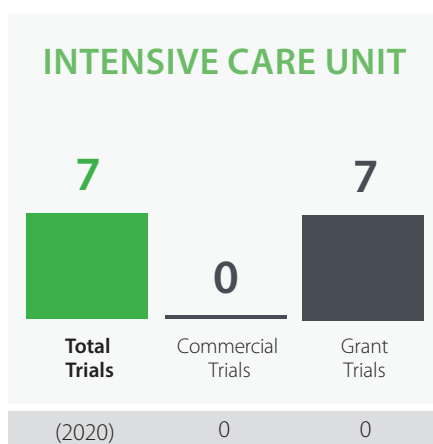
#### CM Health

Mr Simon Manners (Investigator),  
Mr Alpesh Patel (Investigator),  
Mr Andrew Irving (Sub-investigator).

## RESPIRATORY



## INTENSIVE CARE UNIT



## FY21 TOP DEPARTMENTS AT CM HEALTH BY NUMBER OF PROTOCOLS

## RESPIRATORY

### Clinical Lead: Dr Stuart Jones

The Respiratory department have a strong research focus with Dr Conroy Wong having oversight of the research being performed as well as being the Principal Investigator on a large HRC funded Bronchiectasis study. Two new studies focusing on asthma, led by Dr Elaine Yap, have also recently been setup. The focus for the department is varied but includes Bronchiectasis, Asthma, Chronic Obstructive Pulmonary Disease and Interstitial Lung Disease.

### RESEARCH TEAMS

#### MMCT:

Mandy Ma (Research Nurse),  
Lauren Fernyhough (Research Nurse).

#### CM Health:

Dr Conroy Wong (Investigator),  
Dr Elaine Yap (Investigator),  
Dr Paul Dawkins (Investigator),  
Dr Stuart Jones (Investigator).

## INTENSIVE CARE UNIT

### Clinical Lead: Dr Alex Kazemi

The ICU department has several ongoing studies led by Dr Alex Kazemi and Dr Tony Williams with support from research nurse, Rima Song. The department predominantly carry out randomised controlled trials comparing different interventions and their use in reducing mortality and increasing favourable outcomes in critically ill patients. These range from work in resuscitation, community acquired pneumonia and blood infections.

### RESEARCH TEAMS

#### CM Health

Dr Alex Kazemi (Investigator)  
Dr Tony Williams (Investigator)  
Rima Song (Research Nurse)

Department	Commercial	Grant	Total
Allied Health	-	2	2
Cardiology	5	4	9
Clinical Lipidology	2	-	2
Dermatology	1	-	1
Diabetes	6	1	7
Emergency Dept.	-	3	3
Gastroenterology	5	2	7
Haematology	16	9	25
Hepatology	8	-	8
Home Health	-	1	1
Infectious Diseases	-	2	2
Intensive Care Unit	-	8	8
Neonatal	-	2	2
Oncology	-	1	1
Ophthalmology	-	2	2
Orthopaedics	2	-	2
Paediatrics	1	8	9
Plastics	1	2	3
Radiology	2	-	2
Renal	2	3	5
Respiratory	2	4	6
Rheumatology	9	-	9
Surgery	-	1	1
Vaccinology	3	-	3
Womens Health	-	1	1
<b>Grand Total</b>	<b>65</b>	<b>56</b>	<b>121</b>





Principal Investigators Dr Mark Sapsford and Dr Sunil Kumar

**Rheumatologic disorders are often chronic, affect all age groups, and significantly burden the health care system. When these disorders are not diagnosed and treated promptly, they often lead to crippling disability, impaired quality of life, loss of productivity and a resultant economic burden to society.**

If diagnosed early and appropriately treated, most conditions are manageable, and most people can return to the workforce.

Rheumatoid arthritis is one of the most common causes of inflammatory arthritis, affecting approximately 1% of the adult population. It is an autoimmune disease, causing pain, swelling and stiffness in the joints and usually affects the hands, feet and wrists. Rheumatoid arthritis is more common in females than males, with onset usually between 30-50 years. However, it can come on at any age. Synovial inflammation is the hallmark of this disease which results from a complex interaction of genetic and environmental factors, resulting in a breakdown of immune tolerance. In time synovial inflammation can lead to bone and cartilage damage, ultimately leading to deformities. Pro-inflammatory

cytokines play an important role in synovitis. Several cytokines have been implicated in rheumatoid arthritis, including Tumour Necrosis Factor-alpha (TNF $\alpha$ ), interleukins (e.g. IL-1, IL-6, IL-18), and colony-stimulating factors. Treatment of rheumatoid arthritis has traditionally been with conventional disease-modifying drugs, such as methotrexate, but with an improved understanding of the disease, therapeutic agents with specific targets in the inflammatory cascade have been and continue to be developed. Research in the field of rheumatoid arthritis has expanded rapidly in the last few decades, leading to more therapeutic options for rheumatologists and, most importantly, better outcomes for patients. Typical deformities associated with rheumatoid arthritis should be a thing of the past.

The Rheumatology Department at Middlemore Hospital has been involved with clinical trials for more than 20 years, predominantly participating in large commercially sponsored clinical trials. Our research portfolio includes many rheumatic conditions, including axial spondyloarthritis, psoriatic arthritis, gout, systemic lupus erythematosus, giant cell arteritis, and others. The Rheumatology Department was involved in the early anti-TNFα trials, which led to a revolution in treating rheumatoid arthritis. Several anti-TNFα drugs are now available for different rheumatic conditions, and hundreds of people in the Counties Manukau District Health Board region are benefiting from these. Since then, trials at MMCT involving numerous treatments over a range of conditions have now become standard of care.

## Our Staff

We currently have two Principal Investigators (Dr Sunil Kumar and Dr Mark Sapsford) and two study coordinators from MMCT (Mary Paul and Clarence Vivar-Bacani).

We have had a busy year and currently have active trials in:

- rheumatoid arthritis (2)
- psoriatic arthritis (3)
- axial spondyloarthritis
- giant cell arteritis

New trials will be starting in Systemic Lupus Erythematosus, moderate to severe Rheumatoid arthritis and Polymyalgia Rheumatica. Glucocorticoids which are used in a range of rheumatic diseases, have a long list of adverse effects, including but not limited to osteoporosis, diabetes, increased risk of infection, cataracts and mood disturbance. The polymyalgia rheumatica Phase II study will assess the safety and efficacy of a novel agent (an antibody-drug conjugate: a TNF-α drug combined with a glucocorticoid receptor modulator), which if proved safe and effective, while minimising glucocorticoid adverse effects, could be another big step forward in the management of not just polymyalgia rheumatica, but a range of rheumatic conditions.

As a clinician being involved in sponsored pharmaceutical trials has a number of advantages. As principal investigators, we find it stimulating as well as challenging. Being involved in clinical trials allows us to be up to date with cutting edge research and potential new therapeutic agents. Compared to some countries, New Zealand has access to only a limited number of funded treatments, and access to clinical trials gives our patients more potential therapeutic options. It is rewarding to see some of our patients benefit from being involved in clinical trials, particularly when conventional treatments have not been effective for them.

The Rheumatology Designated Research Fund grows through the involvement in commercial trials. This allows the department to contribute to the salary of the Rheumatology research fellow and enable us to sponsor our staff to attend research courses and conferences to benefit the department as a whole. Additionally, the Designated Research Fund will help grow investigator-led research within the Rheumatology Department.

**The Rheumatology Department is very well supported by the Middlemore Clinical Trials team and we look forward to working with them for future studies.**

# TRUST OUTCOMES

Middlemore Clinical Trials is a Charitable Trust. Our Charitable Trust status requires that we demonstrate ongoing investment in research initiatives and capability building within CM Health.

Trust funds are held as either general reserves or departmental funds.

## Designated/Restricted Reserves

Whilst Commercial/Grant trials are in progress, the aggregate surplus in both segments is deemed part of total departmental funds. However, these amounts do not formally vest into a Department's Designated Reserve until a trial closes, hence they are unavailable for granting spend until that time. As at 30 June 2021, Commercial/Grant trials in progress show an aggregate net surplus of \$965 thousand (30 June 2020 \$1.32 million).

Designated/Restricted Reserves may be spent at the discretion of Department heads on research and academic activities consistent with the Trust Deed. In May 2016 the Trustees decided that Departments should spend at least 10% of Departmental Reserves each year.

**As at 30 June 2021, total Designated/Restricted Reserves were \$5.84 Million (30 June 2020, \$5.99 million).**

In the year ending June 2021 seven Departments engaged research personnel which were jointly funded by CM Health and MMCT. The personnel included six Research Fellows, a Research Physiotherapist, Research Nurses and a Research Coordinator across the Gastroenterology, Renal, Cardiology, ICU, Rheumatology, Hand/Upper limb and Kidz First Departments.

## Departmental Breakdown of Granting from Designated/Restricted Reserves

Spend FY21	\$
Research Fellow	156,883
Research Nurse	216,896
Conferences/Seminar	11,767
Publications	1,660

## General Reserves

### Granting spend from General Reserves

Spend FY21	\$
Auckland Regional Biobank	25,000
Sponsorship	7,500

**As at 30 June 2021, total general reserves were \$995 thousand (\$1.08 million, 30 June 2020).**

## Auckland Regional Biobank

A centralised Tissue Bank that is run by The University of Auckland was restructured during the year and as a result Middlemore Hospital was required to contribute to the operating cost. The Trustees believed this is essential for Clinical Research and agree to cover the cost on behalf of Middlemore Hospital.

## Sponsorship

During the Research Week hosted by Middlemore Hospital the trustees approved sponsorship from MMCT for the event. One of the purposes for the event is to promote Research and expand awareness about Clinical Research available at Counties Manukau.

## Granting spend summary from Designated/Restricted Reserves in FY21

Department	Opening Balance 01-Jul-2020 \$	Granting FY21 \$	% of Grant Used %	Closing Balance \$
Cardiology & Capex Restricted Reserve	1,375,087.02	44,324.14	3%	1,213,066.01
Cardiology Designated Reserve	355,554.51			387,850.67
Cardiac Catheter Lab Nurses Education Reserve	19,320.58			19,320.58
Dermatology Research Reserve	19,957.32			31,655.46
Diabetes Reserve	60,014.21			61,408.43
Emergency Care Clinical Research Reserve	47,582.19	1,272.17	3%	46,310.02
Gastroenterology and Hepatology Research Reserve	102,114.13	29,499.96	29%	154,454.86
Haematology Research & Special Purposes Reserve	872,874.20	600.00*	0%	860,510.20
Home Health Reserve	20,333.57			20,333.57
Intensive Care Unit Reserve	403,427.66	9,240.02	2%	393,927.64
Infectious Diseases Research and Education Reserve	96,495.08			100,091.47
Kidz First Research Development Reserve	1,291,729.36	298,322.27	23%	1,196,751.89
Spinal Unit Reserve	24,318.73			24,318.73
Microbiology Reserve	17,843.49			17,843.49
Neonatal Research Reserve	31,509.74	1,250.00	4%	53,300.88
Oropharyngeal Department Reserve	5,331.82			6,924.30
Hand and Upper Limb Research	162,105.05	49,176.92	30%	156,184.65
Radiology Research Reserve	2,163.22			2,163.22
Renal Reserve	127,297.99	29,499.96	23%	72,726.62
Respiratory Research Reserve	667,323.50	4,292.38	1%	708,769.25
Rheumatology Research Reserve	240,430.48	29,499.96	12%	255,431.90
Stroke Outcomes Reserve	50,920.44			50,920.44
Womens Health Reserve	54.01			54.01
AT&R Research Reserve	288.8			288.80
Orthopaedics Reserve (new)				3,037.50
Plastics Reserve (new)				1,200.00
Midwifery Reserve (new)				1,300.00
<b>Total</b>	<b>5,994,077.10</b>	<b>496,977.78</b>	<b>8%</b>	<b>5,840,144.59</b>

\*The Haematological Department designated reserve also spent \$211,000 on the sponsorship of haematological clinical trials.

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**Te Kohinga Ora**

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