



# Annual Report 2018

## Middlemore Clinical Trials

Performance Indicators	2
Executive Overview	4
Our story	6
What we do	8
Benefits of what we do	14
Key areas of research	17
Spotlight on Malignant haematology	22
MMCT Trust Outcomes	24



# Sixty one commercial trials FY18



3

Paediatric



11

Diabetes



15

Haematology



2

Renal



9

Rheumatology



6

Cardiology



7

Gastroenterology



4

Respiratory



4

Radiology

## Cover image:

**Mase Taleleu:** Mase has participated in two clinical trials at MMCT

# Performance indicators FY18

**42**

Total Staff

**24**

Research Staff

**235**

New Trial Participants

**549**

Total Trial Participants

**3587**

Outpatient Visits

**\$1m**

Estimated Money Saved.  
Service Outpatient Visits

**9.5%**

Designated/Restricted Reserves spent

**\$1.4m**

Grant Revenues

**\$7.2m**

Total FY18 Revenue

**\$8.5m**

FY18 Reserves

# MMCT Chair's foreword

Dear supporters & stakeholders,

Looking back on 2018 gives us a chance to celebrate some incredible achievements.

Our team at Middlemore Clinical Trials have done an extraordinary job again this year, and this report is a chance for you to share in their successes. As Chair of the Board, I couldn't be more proud of what the organisation has achieved, and I know it's testament to all the hard work and dedication of our highly skilled team.

This was my last year on the Board, so it's especially timely for me to look back and see how we have evolved, as well as look forward to where we are headed as an organisation. One of my key priorities has been to professionalise the Board with highly skilled Trustees. Our board table has also benefited from an unprecedented level of support from Counties Manukau Health with both Dr Gloria Johnson and Margie Apa as Trustees. Their ongoing commitment to the Trust means that we have had, and continue to have, a deep connection to CM Health that is essential to us achieving our charitable purpose. We are committed to supporting the growing research culture at CM Health and funding research that benefits our local population and beyond.

The Trustees have a goal of granting \$1M research funding per year. This means that a priority for the board has been to ensure that the business is positioned for future growth. To this end, we've been fortunate to have Dr John Baker as Clinical and Executive Director of the Trust. However, after a tremendous tenure in the role, this year John announced his intention to scale back his role. As a result, the Trustees conducted a comprehensive review and recruitment process and we were delighted to keep John's talents on the team as Clinical Director and welcome Dr Edward Watson to the helm as our new Chief Executive Officer. These two make a formidable team to take our organisation from strength to strength.

2018 saw the tragic loss of Professor Diana Lennon (Dinny), who was an incredibly talented researcher, paediatrician, and a tireless voice for child health in New Zealand. I first met her when she was leading New Zealand's efforts to combat the devastating Meningococcal B epidemic – which ultimately led to a landmark NZ clinical trial and nationwide roll-out of the MenzB vaccine. And of course she was a champion of one of the largest trials we've ever undertaken at Middlemore Clinical Trials Trust – Prepare RSV. Her passion for research, and her unwavering commitment to voicing/championing the needs of our tamariki is a legacy that we all have a responsibility to pick up, and carry on.

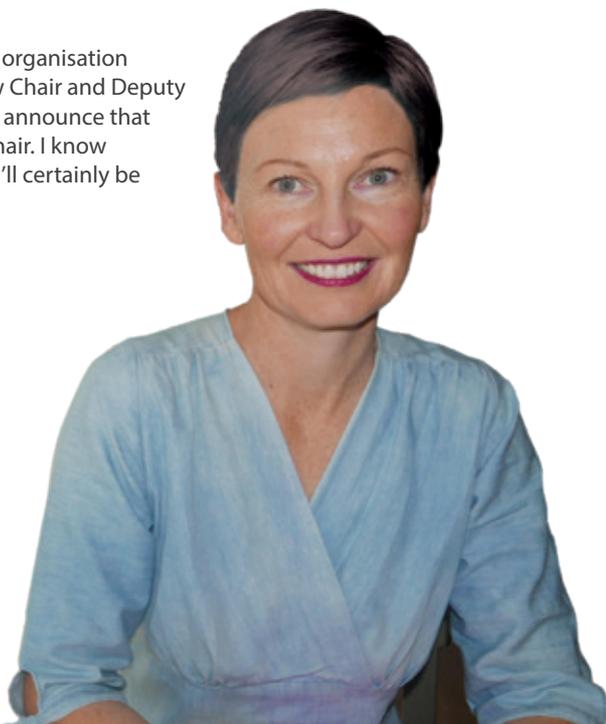
At Middlemore Clinical Trials that means we need to do our part to generate the funds for research grants. And we need a plan for how to invest these precious funds in research that will deliver the greatest benefits. That's why in the coming year Ed will be working with each clinical department to build a research strategy that will set out the goals and objectives for investing designated reserve funds.

Additionally in the coming year there will be a focus of greater engagement with Maori and Pacific communities. This will be achieved with guidance from Dr Isaac Warbrick who for several years has helped Middlemore Clinical Trials with Maori consultation on research proposals.

It's time for me to move on from the Board, and while it's incredibly hard to leave an organisation I feel so passionately about, I know that the skills, energy and enthusiasm of the new Chair and Deputy Chair are precisely what the organisation needs. That's why I'm especially pleased to announce that Greg Batkin will be stepping up to take over as Board Chair, with Gloria as Deputy Chair. I know that under their watch, Middlemore Clinical Trials will go from strength to strength. I'll certainly be supporting the journey every step of the way, and I hope you will too.



**Dr Michelle Sullivan**  
Chair



# Clinical & Executive Director report

Dear supporters & stakeholders,

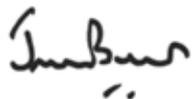
I am pleased to inform you that our total revenue of \$7.23 million and subsequent trading surplus exceeded budget expectation.

Success was driven by a good all-round recruitment effort over the entire commercial clinical trial portfolio. Revenue from grant-funded trials increased from FY17 and revenue from interest earnings on investments was steady. Funds held as general reserves increased slightly to \$2.07 million and funds held as designated/restricted reserves increased to \$6.44 million (total reserves \$8.51 million).

Eleven (11) out of 15 recruiting trials in FY18 met target and 6 trials over-recruited. This is an outstanding achievement.

As the profitability of the business increases, the Trust is turning its attention to increased granting activity from reserves consistent with the aims of the Trust Deed. The Trustees granted 12.2% of general reserves to support a number of projects in FY18. In addition, 9.5% of funds held in designated reserves were granted to support research registrars, research nurses, investigator-initiated research projects, research equipment and academic activities. They have also published a granting strategy in May 2018 to assist future allocation of funds.

We have high hopes for the year ahead with further growth of revenue as we make the most of existing opportunities and expand the scope of our business into new therapeutic areas. We will continue to recruit new research nurses as the business expands.



**John Baker**

Clinical & Executive Director



# Our story

Middlemore Clinical Trials (MMCT) is a charitable trust established in 2001 that administers commercial clinical trials and major grant-funded research studies on behalf of Counties Manukau Health.

We are independent of the district health board with an independent board of Trustees. Our business brings high quality pharmaceutical trials to the people of South Auckland often making available to our patients novel therapies that they otherwise wouldn't have access to. We also provide research facilities and support functions, employ research nurses, and manage the finances of the trials. Surplus funds remaining after trials are completed are held in the Trust's reserves for spending on further research and academic activities consistent with the objectives of our Trust Deed.

MMCT is based at Middlemore Hospital and employs 42 staff. Our staff comprises of highly trained research nurses and support staff including finance, management, phlebotomy, and regulatory affairs.

Our success in building a highly-skilled and motivated research nurse workforce is the key factor driving Middlemore Clinical Trials financial success over the past 2 years. Research nurses need to develop a skill-set incorporating study coordination, patient interaction and support and data management. Recruitment is one of their primary responsibilities and they spend a good deal of their time finding potential participants that fit trial criteria. This is done through a close partnership with the secondary care multi-disciplinary team (MDT), the Principal Investigator, and the Primary Care team. Nurses are often drawn to clinical research because they are excited to be at the cutting edge of new medical developments; they like the thought of being part of the 'bigger picture'; and they enjoy providing improved quality of care for their patients.

Typically, our research nurses are excellent at multi-tasking and managing a diverse portfolio of studies in various stages through the research process: set-up; recruitment; follow-up; and close out.

**42** Staff and contractors



**Staff with more than ten years service to MMCT.** (Left to right) Jo-Ann McLeish, Chris Giffney, Catherine Howie, Diane Caveney, Ruth Cammel, Penelope Eadie.



Lara Sharp

MMCT  
Phlebotomist

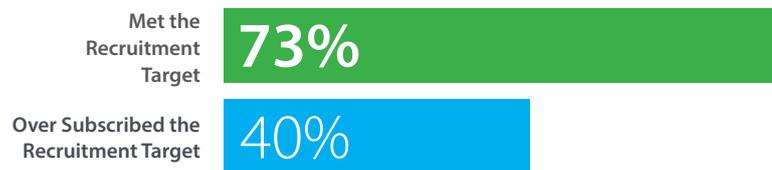


# What we do

MMCT is one of the leading commercial clinical trial sites in Australasia.

We lead the recruitment of participants into most of the clinical trials that we participate in and pride ourselves on generating high-quality data for our sponsors. Reasons for our success are the high prevalence of patients with long-term health conditions in our health district, the willingness of our local population to support research and strong support of our District Health Board, Counties Manukau Health. Our flexible work model allows us to change nurse responsibilities and double or triple numbers of nurses working on a particular trial during the critical study enrolment period to ensure we meet recruitment targets.

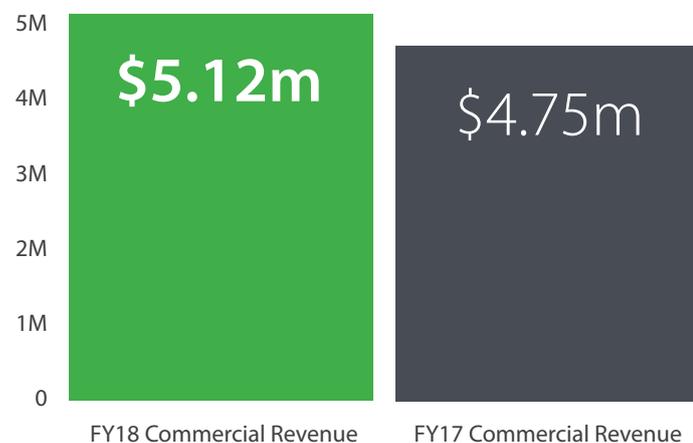
## Clinical Trial Recruitment Performance FY18



## MMCT Commercial Revenue

It is a sign of the strength of the market and the continuing strong demand for our services that we have been able to achieve an 8% increase in total commercial trial revenue from the previous financial year.

## Clinical Trial Revenue Performance FY18



## Our Clinical Trials

Keeping our clinical trial portfolio current is a commercial imperative for MMCT and our investigators. By the end of the financial year we were administering 61 commercial trials and 65 grant-funded studies at Middlemore hospital. Our commercial trials are predominantly drug trials of experimental new medicines reflecting the interests of our investigators, although we also do a small number of device trials. There was a higher proportion of early phase (Phase 1 and Phase 2) trials started in FY18 compared to the previous financial year.

## Top Recruiting Departments at CM Health in FY18

Department	Number of Active trials	Number of Participants
Diabetes	11	192
Paediatrics	3	119
Cardiology	6	74
Haematology	15	51
Renal	2	37
Rheumatology	9	36
Gastroenterology	7	16
Interventional Radiology	4	13
Respiratory	4	11
<b>TOTAL</b>	<b>61</b>	<b>549</b>

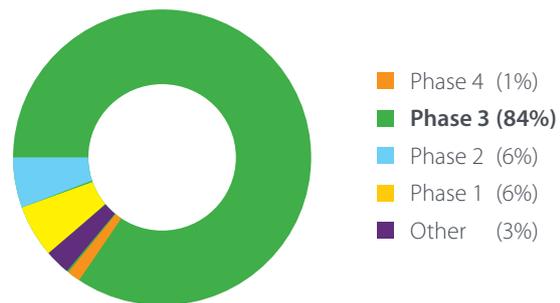
## Investigators

Our investigators are CM Health senior medical consultants. There are 22 investigators working on commercial trials, but there has been a big increase in new investigators for investigator-led studies from 36 to 45. In FY18, we had 58 investigators engaged in research activities representing 20 departments within the hospital.

## 2018 commercial trials by study phase



## 2017 commercial trials by study phase

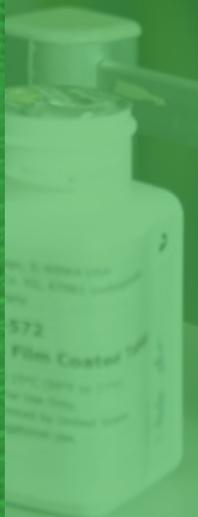


**61** Active Commercial Trials in FY 2018



Linda Chiu

MMCT  
Clinical Trial  
Pharmacist



## Grant funded trials

Many hospital departments engage in grant funded research trials. The majority of these trials are initiated elsewhere, either as international network studies or as public-good Health Research Council (HRC) funded studies and Middlemore hospital operates as a collaborating site.

### Grant funded trials - centre of initiation breakdown

Department	Initiated at CM Health	Initiated elsewhere	Total	% of grand total
AT&R		1	1	1.5%
Cardiology		4	4	6.0%
Diabetes	2	2	4	6.0%
Home Health		1	1	1.5%
Emergency Dpt.	1	2	3	4.5%
Haematology		10	10	15%
Infectious Disease		1	1	1.5%
Intensive Care		9	9	14%
Microbiology		1	1	1.5%
Neonatal	3	4	7	11%
Paediatrics	2	7	9	14%
Plastics	1	2	3	4.5%
Renal	3	2	5	8.0%
Respiratory	1	2	3	4.5%
Stroke		1	1	1.5%
Women's Health		3	3	5.0%
<b>Grand Total</b>	<b>13</b>	<b>52</b>	<b>65</b>	<b>100%</b>

**13** Grant funded trials initiated at CM Health in FY18

## SHIVERS

SHIVERS is a long-term surveillance study that investigates patients admitted to hospital in metro Auckland with severe acute respiratory infections caused by influenza and other respiratory pathogens. The study began in 2012. The principal objective is to better understand disease burden, epidemiology, aetiology, immunology, risk factors for severe and mild illness, effectiveness of vaccination and other prevention strategies for influenza in the Auckland region. Funded by a grant from the Centres for Disease Control (USA), SHIVERS is locally administered by Institute of Environmental Science and Research (ESR). Additional funding has been received from GlaxoSmithKline. Lead local investigators are Dr Conroy Wong (Respiratory Physician), Dr Adrian Trenholme (Paediatrician), and Dr Susan Taylor (Microbiologist).

## RESOLVE

RESOLVE is a pragmatic cluster-randomised, open-label trial that randomises dialysis sites to two different default dialysate sodium concentrations. Sponsored by the George Institute for Global Health in Sydney, it is funded locally by the Australian National Health and Medical Research Council and the New Zealand HRC. The New Zealand lead investigator is Dr Mark Marshall (Nephrologist). The trial design allows evaluation of health service practice in real-world conditions including sicker and more vulnerable patients who typically do not participate in individually randomised trials.

## PACIFIC ISLANDS FAMILIES STUDY (PIFS):

Respiratory Health of Pacific Youth: Risk and Resilience throughout Childhood. The PIFS respiratory study is funded by an HRC grant to AUT University. The study commenced recruitment in early 2018. Dr Conroy Wong (Respiratory Physician) is co-investigator and clinical lead. PIFS respiratory looks at early-life risk and protective factors on lung function attainment and respiratory outcomes amongst 800 adolescents from the PIFS birth cohort of 1,398 Pacific children born in South Auckland in 2000.

## KIWI

KIWI is a multi-centre, single-arm, open-label, network study of Kyprolis (Carfilzomib) and dexamethasone followed by autologous bone marrow transplant and carfilzomib, thalidomide and dexamethasone consolidation in newly diagnosed patients with multiple myeloma. Sponsored by the Waitemata District Health Board, KIWI is led by local haematologists. Study drug (carfilzomib) is supplied by Amgen. The Principal investigator is Dr David Simpson, North Shore hospital, and Dr Rajeev Rajagopal is lead local investigator.

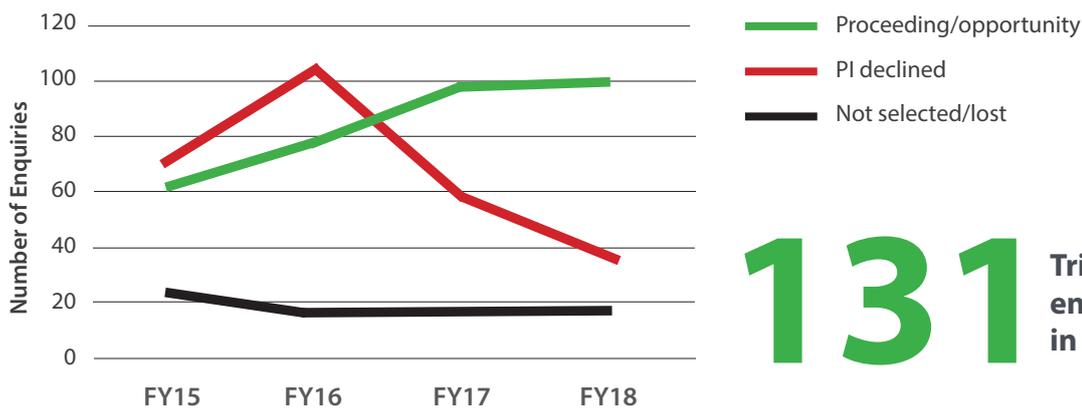
## Business Development

Our business development team led by our Director of Client Services actively markets MMCT and CM Health as a site for commercial research trials with pharmaceutical industry sponsors and contract research organisations in Australia and the USA.

### New Trial Feasibilities Received in 2018

Speciality	Phase I	Phase II	Phase III	Phase IV	Unknown	Grand Total
AT&R			1			1
Cardiology		2	5	1		8
Dermatology			5			5
Diabetes	1		6	1		7
Emergency Dept		1				1
Gastroenterology	1	5	4		2	12
Haematology	3	7	7	1	1	19
Hepatology	3	3	2			8
Infectious Disease		2	1			3
Intensive Care	1	1	4			6
Mental Health		2		1		3
Neonatal			1			1
Oncology	1		3		1	5
Ophthalmology			2			2
Otorhinolaryngology (ENT)		1				1
Paediatrics	4	3	2			9
Renal		3	1		1	5
Respiratory		7	6	1	2	16
Rheumatology			11	1		12
Stroke		1	1		1	3
Womens Health	2	1	1			4
<b>Grand Total</b>	<b>16</b>	<b>39</b>	<b>63</b>	<b>5</b>	<b>8</b>	<b>131</b>

### New Trial Enquiries from FY15 to FY18



**131** Trial feasibility enquiries received in FY18

FY18 saw a continued increase in commercial trials proceeding. Revenues grew to \$7.2m. Funds for research grew to \$8.5m. Funding spent on grants grew to \$805k.

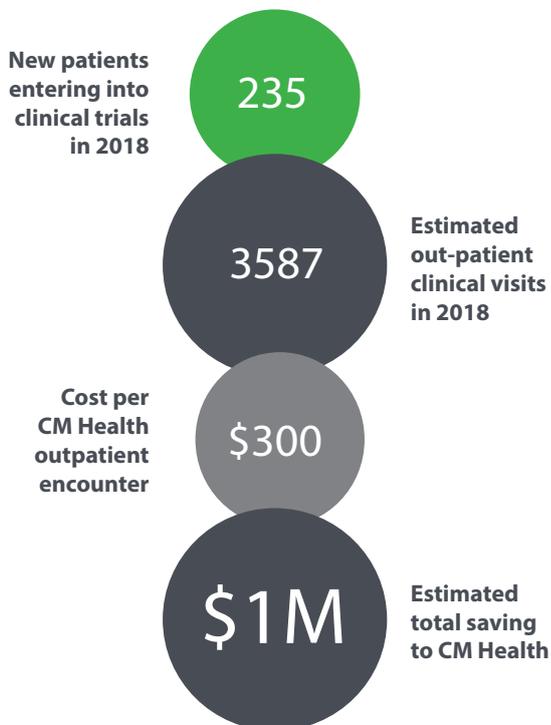
These trends affirm we are on the right path for conducting business.

**62%** Feasibilities proceeded to evaluation in FY18

# Benefits of what we do

Most of the drug trials conducted at MMCT are late clinical stage (Phase III) studies where drug safety (toxicity) issues have largely been resolved and sponsors are collecting data to support a successful registration application (NDA review). This means participants with long-term conditions can receive high-quality, protocol-driven healthcare at sponsor's expense over many years at considerable saving to the New Zealand public health system. Additionally our patients get access to novel medicines that they otherwise can not access through the public health system.

We estimate 3,587 outpatient clinic visits were saved in FY18 with patients attending clinical trial visits rather than CM Health outpatient clinic appointments. At an estimated cost of \$300 per clinic appointment, this equates to a potential cost saving of up to \$1 million per annum.



**\$1m** Estimated total saving to CM Health



Anne Kendall

MMCT  
Research  
Nurse

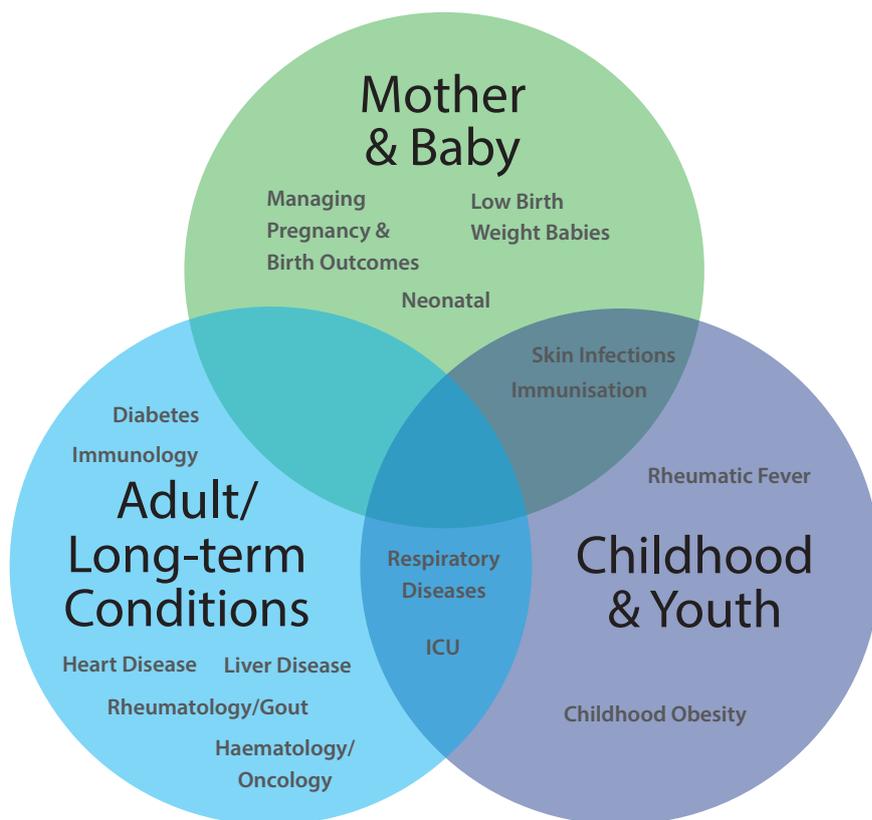


# Research strategy

Designated/restricted reserves are designed to enhance and grow departmental research capability at CM Health and capacity to perform clinical research.

Additionally, these reserves can be used to address research questions determined by an individual department. The Board of Trustees published a research strategy in May 2018. The purpose of the research strategy was to ensure that research granting is aligned with health and strategic priorities of CM Health. This is consistent both with the Trust Deed and with the relationship agreement with CM Health that was signed in July 2015. The Board of Trustees has set two goals for granting: (i) clinical impact on local and regional health disparities; and (ii) research capacity and capability building.

Grant proposals requesting funds from departmental funds (designated reserves) must meet one of the goals and one of the areas of priority to be considered for granting. Money within Trusts should not be left to accumulate, but rather they should be employed to grow research potential within the department.



# Middlemore Clinical Trials key areas of research 2018



## Paediatric

The Paediatric team led by Dr Adrian Trenholme have had another outstanding year with one large highly successful commercial clinical trial and a portfolio of grant-funded studies. The team mourned the passing of Professor Diana Lennon in May 2018. Dinny was co-principal investigator on many research studies and she must be given the credit for the tremendous research advances made by the paediatric team over the past several years.

**MMCT** – Fay Sommerville (research nurse), Dr Rebecca Thompson (sub-investigator),

**CM Health** – Dr Yiing Yiing Goh (sub-investigator), Dr Flo Mow (sub-investigator), Marie Wilson (midwife), Naomi Apel (midwife), Adrienne Priday (contractor),

Emma Collis (research nurse), Mandy Retter (research nurse), Judith Johnson Niuelua (midwife), Shirley Lawrence (research nurse).



## Haematology

The haematology team led by Dr Sharon Jackson continues to maintain a highly active research program that provides a good blend of commercial trials and investigator-initiated network studies. These trials provide patients with access to medicines that otherwise are not available in New Zealand.

**MMCT** – Alice Cassidy (research nurse), Yiling Ge (research nurse), Smita Charles (research nurse), Chris Giffney (research nurse).

**CM Health** – Dr Samar Issa (investigator), Dr Gordon Royle (investigator), Dr Hilary Blacklock (investigator), Dr Rajeev Rajagopal (investigator), Martyn James (research nurse).





# Diabetes

The diabetes team led by Dr Brandon-Orr Walker works closely with DHB clinicians to undertake a large number of commercial sponsored clinical trials. In 2017/2018, they started several new trials in diabetic kidney disease and a large diabetes in pregnancy registry project that was privately sponsored.

**MMCT** – Dr John Baker (investigator), Ruth Cammell (research nurse), Amy Cryer (research nurse), Sarah Baresic (research nurse), Reniza Ongcoy (research nurse), Yiling Ge (research nurse), Paula Massey (research nurse), Penelope Eadie (research nurse), Jamie Duckworth (research nurse), Eulyee Ahn (research nurse), Arti Kumar (research nurse), Susan Ross-Heard (midwife).

**CM Health** – Dr Brandon Orr-Walker (investigator), Dr Ian Rosen (investigator), Dr Renate Koops (investigator), Dr Carl Eagleton (investigator).



# Cardiology

The cardiology team is led by Dr Selwyn Wong. There has been something of a hiatus in commercial trial opportunities over the past several years, but investigator-initiated research in cardiology remains strong.

**MMCT** – Diane Caveney (research nurse), Lynette Pearce (research nurse), Mandy Ma (research nurse).

**CM Health** – Dr Douglas Scott (investigator), Dr William Harrison (investigator), Dr Mayanna Lund (investigator), Dr Andrew Kerr (investigator), Dr Selwyn Wong (investigator), Dr Jamie Voss (investigator).

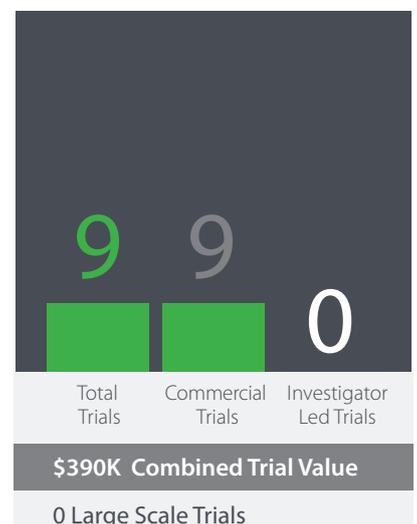


# Rheumatology

Rheumatology research continues to be very active at MMCT and CM Health under the leadership of Dr Sunil Kumar. There has been a paradigm shift in standard care of many conditions such as rheumatoid arthritis with a number of innovative new treatments.

**MMCT** – Cecilia Paul (research nurse), Sandy McGreevy (research nurse), Smita Charles (research nurse), Lea Charlesworth (research nurse), Arti Kumar (research nurse).

**CM Health** – Dr Sunil Kumar (investigator), Dr Rajiv Gupta (sub-investigator).





# Renal

There was a rekindled interest in commercial trials in renal medicine in 2017/2018 under the leadership of Dr Christopher Hood. Dr Mark Marshall continued his interest in academic research with several large Health Research Council studies.

**MMCT** – Brenda Luey (research nurse), Penelope Eadie (research nurse), Jamie Duckworth (research nurse), Lea Charlesworth (research nurse), Arti Kumar (research nurse).

**CM Health** – Dr Christopher Hood (investigator), Dr Daniel Lin (sub-investigator), Dr Viliami Tutone (sub-investigator), Dr Jonathan Hsiao (sub-investigator), Dr Hari Talreja (sub-investigator), Dr Angus Turnbull (sub-investigator), Dr Jamie Kendrick-Jones (sub-investigator), Dr Elene Ly (sub-investigator), Dr Hla Thein (sub-investigator), Dr Michael Lam (sub-investigator), Dr Mark Marshall (investigator), Dr Rachel Walker (investigator).

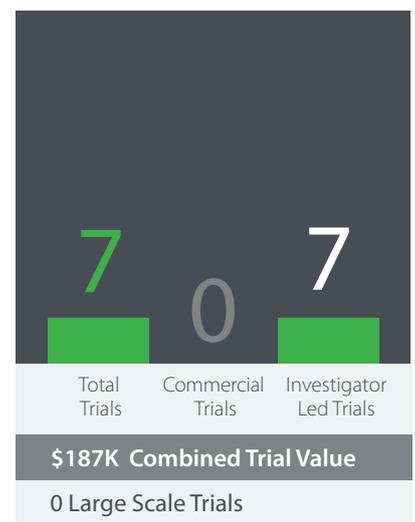


# Gastroenterology

This year has seen a resurgence in hepatology research at MMCT and CM Health under the leadership of Dr Alasdair Patrick. Dr Tien Huey Lim (hepatologist) is working closely with Professor Ed Gane (Auckland Clinical Studies) to attract more early-phase trials to MMCT.

**MMCT** – Ruth Cammell (research nurse), Sandy McGreevy (research nurse), Smita Charles (research nurse), Lea Charlesworth (research nurse), Arti Kumar (research nurse).

**CM Health** – Dr Tien Huey Lim (investigator), Dr Ashok Raj (sub-investigator), Dr Judy Huang (sub-investigator), Dr Hannah Giles (sub-investigator), Dr Sum Lo (sub-investigator).





Alice Cassidy

MMCT  
Research  
Nurse

# Publications from research funded by MMCT Trust

1. **Wong C, Chang CL, Vandal A et al.** Tiotropium treatment for bronchiectasis (ROBUST): a randomised, placebo-controlled, crossover trial. European Respiratory Society – Poster presentation.
2. **Wong C** (for ROBUST Study Investigators). Inhaled tiotropium treatment for bronchiectasis: the ROBUST study. Grand Round Presentation, 7th December 2017.
3. **Dissanayake AM, Wheldon MC, Hood CJ.** Pharmacokinetics of metformin in patients with chronic kidney disease stage 4 and metformin-naïve type 2 diabetes. *Pharmacol Res Perspect* 2018;e00424. <https://doi.org/10.1002/prp2.424>.
4. **Robinson H, Jarrett P, Norton S, Broadbent E.** The effects of psychological interventions on wound healing: | A systematic review of randomised trials. *Br. J. Health Psychology* 2017. 22(4): 805-35.
5. **Robinson H, Ravikulan A, Nater UM, et al.** The role of social closeness during tape stripping to facilitate skin barrier recovery: Preliminary findings. *Health Psychology* 2017. 36 (7): 619-29.
6. **Robinson H, Jarrett P, Vedhara K, Broadbent E.** The effects of expressive writing before or after punch biopsy on wound healing. *Brain, Behav Immun.* 2017.61:217-22.
7. **Sekra A, Schauer C, Mills L et al.** Chromoendoscopy versus standard colonoscopy for detection of nonpolypoid dysplasia in patients with inflammatory bowel disease. *NZMJ* 2018 131:1478.
8. **Hajje E, O'Brien C, Coomarasamy C, et al.** Integrated care pathway (ICP) for discharge preparation of patients with diabetes (PWD). International Diabetes Federation (IDF) 2017 Congress, Abu Dhabi – poster presentation
9. **Hanna MZ, Kalev-Zylinska ML, Jackson SR et al.** Distinctive features of polycythaemia vera in New Zealand Polynesians. *NZMJ* 2018;131:38-45.
10. **Taylor E, Zeng I, O'Dochartaigh C.** The reliability of the Epworth Sleepiness Score in a sleep clinic population. *Journal Sleep Research* 2018 <https://doi.org/10.1111/jsr.12687>
11. **Hayward J.** Obesity and subsequent weight gain in children hospitalised with acute rheumatic fever. Lancefield International Symposium on Streptococci and Streptococcal Diseases, 2017
12. **Hayward J.** Obesity and subsequent weight gain in children hospitalised with acute rheumatic fever. Paediatric Society of New Zealand Annual Scientific Meeting, 2017
13. **Furlow B.** Rituximab does not improve outcomes in primary CNS lymphoma. *Lancet Oncology* 2018; accepted.
14. **Moreau P, Masszi T, Grzasko N et al.** Oral ixazomib, lenalidomide, and dexamethasone for multiple myeloma. *N Eng J Med* 2016; 374:1621-34
15. **Mateos MV, Masszi T, Grzasko N et al.** Impact of prior therapy on the efficacy and safety of oral ixazomib-lenalidomide-dexamethasone vs placebo-lenalidomide-dexamethasone in patients with relapsed/refractory multiple myeloma in TOURMALINE-MM1. *Hematologica* 2017;doi:10.334/haematol.2017.170118.
16. **Pollack CV, Reilly PA, van Ryn J et al.** Idarucizumab for dabigatran reversal – full cohort analysis. *N Eng J Med* 2017;377:431-41.

# Spotlight on malignant haematology

Oncology trials are provided in Auckland as a regional service. However, MMCT continues to provide malignant haematology trials from the haematology day stay ward. MMCT administered 26 haematology trials at Middlemore in FY18 with 51 participants.

Clinical Head of Haematology, Dr Sharon Jackson says ...

As a Department we believe that access to good quality clinical trials should be standard of care for our patients. We are very keen to give patients with haematological malignancies the opportunity to enrol in clinical trials that offer them access to novel therapies not funded in NZ.

Haematology is a rapidly evolving field in terms of the basic science, our understanding of the molecular basis of disease and translational research. New therapies offer patients the hope of an improved outcome (i.e. improved survival and/or quality of life) and we see giving patients access to those therapies as very important. Over the past couple of years we have been enrolling patients in clinical trials for diseases such as Myeloma and Chronic Lymphocytic Leukaemia, Chronic Myeloid Leukaemia, and Myelofibrosis. One CLL trial with 2 novel drugs has seen patients achieve responses that have not been seen before with traditional chemotherapy so patients are very keen to take part. There is the immediate clinical benefit they derive, but also they feel that they are contributing to the advancement of scientific knowledge overall, even if it doesn't benefit them directly.

Over the years, we have seen new treatments develop that completely change the standard of care for patients. For example, 20 years ago there were the first clinical trials with the tyrosine kinase inhibitor imatinib which completely changed the way we treat chronic myeloid leukaemia. Over the last 5 to 6 years several new drugs are having a similar impact on the way we treat Chronic Lymphocytic Leukaemia. This means we can potentially shift from a primarily chemotherapy based regimen to a non-chemotherapy based regimen which offers quite a few advantages to patients such as avoiding drugs that potentially damage their bone marrow stem cells and lead to other complications longer term. Many of these new therapies are primarily oral treatments that can be given to patients in the clinic setting. Patients in the Chronic Lymphocytic Leukaemia clinical trials we have been involved with here at Middlemore have said the study medication they've been taking has been like a miracle drug – being on the study has changed their quality of life dramatically, giving them the opportunity to return to work or go off on holiday. This is very rewarding for patients as well as for the clinical staff caring for those patients.

One of the trials that we are most proud of is a study that originated here at Middlemore. This study has just been presented at the American Society of Haematology meeting and is due to be published in the medical journal Lancet Oncology.

One of the key philosophies we try to embed within the Department is that research is part of what we do every day. We try to integrate research into the standard practice in our inpatient and outpatient units. All of our staff derive quite a lot of personal satisfaction from the long term relationships they have with the patients on clinical trials, as well as seeing the benefits the patients derive from the novel therapies they wouldn't otherwise have access to. The ability to do clinical research certainly enhances the overall experience for both our medical and nursing staff.



Haematology and Day Unit Staff 2018

## Haematology trials include:

- Mantle Cell Lymphoma
- Diffuse Large B-Cell Lymphoma
- Chronic Lymphocytic Leukaemia
- Follicular Lymphoma
- Treatment Naive Multiple Myeloma
- Relapsed Refractory Multiple Myeloma

## Compounds which we work with include:

### IV Administered

- Anti- CD20 mAb
- Anti-CD19 mAb
- Alkylator
- Proteasome inhibitor
- PD-1 receptor inhibitor
- Anti- CD38 mAb

### Oral Administered

- Tyrosine Kinase Inhibitor
- Bci-2 inhibitor
- iMID
- Corticosteroids

# Patient Stories



## **Michael Niellwendyk**

**Michael suffers from multiple myeloma**

"I am extremely grateful to (trial sponsor) for the opportunity to be part of their trial as with my high risk factors the outlook without new remedies is bleak. The opportunity for New Zealanders to be part of worldwide trials using the latest evolving drug regimens is fantastic."



## **Osiuolo Lama**

**Osiuolo has multiple myeloma.**

**He is participating in a MMCT Trust funded study**

"Everything was well explained, easy to read, (and) all good. Since starting the trial, I felt since my first treatment until now I feel better and my numbers are showing it is getting better. I made the right decision to go on the trial. Yes, 100% I would recommend it to anyone I came across."



## **David Palmer**

**David has chronic lymphocytic leukaemia.**

"My journey started with getting CLL and having the normal treatment twice and it coming back very severely. At that stage, there wasn't much more that could be done. I was very unwell. Luckily, I got into a trial here at Middlemore and I got very much better. I can't recommend it too highly. Everyone's been absolutely wonderful and very supportive."



## **Mase Taleleu**

**Mase has participated in two clinical trials**

"In 2008 I got sick. I had a fall outside our house. While I was in hospital, a girl took some bone marrow from my back. They said that I had Multiple Myeloma. I didn't know what to say because it was a surprise to me as I didn't know I had cancer. The clinical trial started in 2015. I'm still taking all my medications and the result of the myeloma is (very good)."

# MMCT Trust outcomes

Middlemore Clinical Trials is a Charitable Trust. Our Charitable Trust status requires that we demonstrate ongoing investment in Public Good activities.

Trust funds are held as either general reserves or designated/restricted reserves. Surplus funds remaining after commercial clinical trials are completed and costs are deducted, are allocated to designated reserves.

## Designated/restricted reserves

Designated reserves for use by specific departments were \$6.44 million at the end of FY18.

Designated reserves may be spent at the discretion of department heads on research and academic activities consistent with the Trust Deed. In May 2016, Trustees decided that departments should be obliged to spend at least 10% of Designated reserve balances each year consistent with the Trust Deed.

## Granting from Designated/Restricted Reserves in FY18

Expense Category	Allocation	% of total
Research Registrars/Fellows	\$230,393	41.1%
Research Nurses	\$117,506	21.0%
Research costs	\$29,073	5.2%
Courses and conferences	\$64,588	11.5%
Equipment	\$111,740	20.0%
Publications	\$2,939	0.5%
IT costs	\$3,795	0.7%
<b>TOTAL</b>	<b>\$560,034</b>	<b>100%</b>

CM Health and MMCT jointly fund up to 6 research registrar positions distributed between Cardiology, Rheumatology, Renal, Gastroenterology, Infectious Diseases and Diabetes departments. In addition, Kidz First appointed a 1-year full time senior research fellow in 2017 (Jodie Hayward). Dr Hayward has completed a project on obesity in children hospitalised with acute rheumatic fever. Dr Hayward has been involved in setting up Kidz First Hospital as a local site for a multi-centre double blinded randomized control trial on community acquired pneumonia in indigenous children in developing countries.

## Departmental breakdown of granting from Designated/Restricted Reserves

Speciality	Opening balance 30-Jun-17	Granting FY18	% used
Microbiology	\$90,862	\$62,120	68.4%
Kidz First	\$446,552	\$190,261	42.6%
Rheumatology	\$230,253	\$74,658	32.4%
Plastics	\$189,346	\$47,740	25.2%
Renal	\$96,080	\$18,461	19.2%
Gastroenterology	\$188,304	\$24,999	13.3%
Neonatal research	\$46,631	\$4,360	9.4%
ICU	\$204,935	\$18,882	9.2%
Respiratory	\$595,185	\$35,430	6.0%
Haematology	\$630,158	\$26,084	4.1%
Cardiology	\$1,593,215	\$55,220	3.5%
Infectious diseases	\$91,565	\$1,355	1.5%
Diabetes	\$41,570	\$300	0.7%
Stroke	\$30,840	-	0%
Home Health Care	\$27,173	-	0%
Emergency Care	\$19,217	-	0%
Cardiac Cath Lab	\$18,360	-	0%
Dermatology	\$6,892	-	0%
Oropharyngeal	\$5,067	-	0%
AT&R	\$266	-	0%
Radiology	-	\$220	0%
Women's Health	-	-	0%
Mental Health	-	-	0%
General Surgery	-	-	0%
Anaesthetics	-	-	0%

## General Reserves

General reserves were \$2.07 million at the end of FY18.

### Granting from General Reserves in FY18

Expense Category	Allocation
Community Nutrition Trial (AUT)	\$100,000
Nurse/Allied Health Travel Awards	\$5,119
Diabetes in Pregnancy Registry	\$72,752
Research week, prizes and awards	\$7,000
Donation to TUPU Fund	\$50,000
Research Administrator Trainee (April-June)	\$10,211
<b>TOTAL</b>	<b>\$245,082</b>

### Community Nutrition Trial

The Community Nutrition trial co-funded by MMCT and AUT University compares the impact of a low carbohydrate, high fat diet with standard-of-care diet on blood glucose control (HbA1c) in 200 patients with type 2 diabetes and suboptimal control.

### Nurse/Allied Health Travel Awards

Akshat Shah (Speech Language Therapist) was granted \$3,250 to attend the European Cleft Lip and Palate Centres in London, Oxford (UK), Copenhagen (Denmark), and Gotenburg (Sweden) in November 2017. Kirsten Thyse (Physiotherapist) was granted \$1,000 to support attendance at the Australian and New Zealand Spinal Cord Society Annual Scientific Meeting in Brisbane in November 2017.

### Diabetes in Pregnancy Registry (DiPR)

The Freemasons Roskill Foundation donated \$105,832 to support the establishment of the program in 2016 and a further grant of \$41,916 in November 2017. The program involved a 1-year pilot study and collection of retrospective data on 2,500 women who attended diabetes in pregnancy clinic in the previous 5 years. The Middlemore Foundation provided a grant of \$40,250 in April 2018 for the evaluation and cost benefit analyses of the DiPR and a Diabetes Care Support Service Audit of Primary Care. Both evaluations are to be conducted by Professor David Simmons of Western Sydney University.

### Research week, prizes and awards

The MMCT Board of Trustees donated \$7,000 to CM Health Research Office to support Research Week. This included a \$500 best poster prize, and \$500 people's choice award.

### Donation to TUPU Fund

The MMCT Board donated \$50,000 to the CM Health Research Office towards the TUPU fund. The TUPU fund provides small project grants of up to \$30,000 to CM Health investigators for investigator-initiated research.

### Research Administrator Trainee (April-June)

In 2017, the Board of Trustees approved funding for a 1-year trainee role to provide a career development pathway for graduates of the University of Auckland Masters of Bioscience Enterprise programme. Chaewoo Jun was appointed in April 2018.

# \$805K

Was distributed from the Trust in FY18



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Clinical Trials

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