



Middlemore Clinical Trials

ANNUAL REPORT

2020

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.

MMCT is an independent charitable trust established in 2001 that administers both commercial and grant funded research on behalf of the local District Health Board, Counties Manukau Health

Working with over 22 departments we provide a centralized service for all types of trials from Phase I to Phase IV. 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.

MMCT staff are comprised of experienced, highly trained research nurses, co ordinators and support staff including: finance, management, IT, phlebotomy, dedicated pharmacy and a Senior Regulatory Officer. As we focus purely 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.

We are passionate about bringing more research to New Zealand so that our community and participants can benefit from the opportunity to be part of leading edge science and novel therapies from around the world.

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.**

# FOREWORD

## From the Chair

The year has been one of challenges as the team developed a pipeline of trial opportunities to fill the gap left by a major trial completing successfully, and then dealt with the challenges brought by the emergence of COVID-19 and the impact of Alert Levels 4, then 3, in March and April.

The team did an extraordinary job maintaining the care of the participants on trials that were underway when the country was placed into level 4 (recruitment of new participants was largely suspended over this period). A benefit of the disruption this caused, was an increasing focus on new ways of doing things, particularly remotely and with a focus on reducing the amount of physical face to face contact or visits to Middlemore Clinical Trials (MMCT). While the threat of further disruption caused by this pandemic is unlikely to be far away for the foreseeable future, these initiatives will continue to be important.

At the end of November 2019, our Deputy Chair Gloria Johnson retired. Gloria joined the Board in February 2016 and became Deputy Chair in 2018. The Trustees thank Gloria for her input and wise counsel and wish her well in whatever the next phase of her career brings. Following Gloria's retirement we welcomed Counties Manukau DHB's Chief Medical Officer Dr Peter Watson to the Board.

Over the 2020 financial year, it has been pleasing to see departments at Middlemore that have not traditionally been research partners with MMCT becoming more involved in clinical research. These endeavors will ultimately lead to greater spread of designated reserves which can be granted to fund research, further benefiting the community to which MMCT belongs.

Similarly, MMCT now has a much broader base of sponsors and CRO's that it deals with on a regular basis, than it did twelve months ago. Overall the number of sponsors and CRO's that MMCT deals with on a regular basis has increased by 10%, however within this the number of CRO's has increased by over 25%. This will ultimately lead to more trials across a broader range of clinical areas.

On a per capita basis, New Zealand attracts much less research than Australia does. Ed and the MMCT team are involved with the rest of the community of clinical research units in New Zealand who are working together with NZTE to attract a greater share of clinical research to New Zealand.

The Trust's performance reflects the hard work and dedication of the team, at all levels particularly given the challenges COVID-19 has brought this year. The board look back with satisfaction on the 2020 financial year, and look forward in anticipation to the results of the above initiatives in coming financial years.



**Greg Batkin**

CHAIR



Due to COVID-19 travel restrictions, the above image is a composite created for this report.  
Trustees (left to right) – Margie Apa, Michael James, Kevin Wightman, Greg Batkin (Chair), Marama Parore, Peter Watson

# YEAR IN REVIEW

## From the CEO

Like all business throughout New Zealand and indeed the world this year will be forever linked to the global pandemic of COVID-19. In such times the success or otherwise of any clinical trial unit will depend on the resilience of its staff, their passion for what they do, the belief of the sponsor in the value the unit offers and the experiences of the trial participants.

Throughout the year with the help of our committed sponsor partners and a District Health Board that is committed to growing research, we have brought more trials than ever to the community of Counties Manukau. This has meant access to breakthrough treatments to diseases such as lymphoma, hepatitis B, psoriatic arthritis, bronchiectasis, severe lipid disorders and many others.

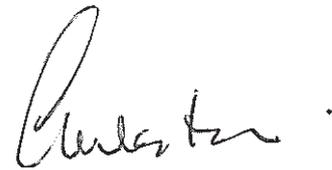
Our continuous surveying of participants' indicates all would recommend being on a clinical trial to their friends and whānau who have a medical condition.

Half of the work we do is clinical trials funded through public and private grants. These Grant trials create significant enthusiasm amongst research staff as they are often bespoke to the community or the researchers involved. With a greater understanding as to how to grow such trials we look forward to supporting more such research for the investigators and participants involved.

The opening of our dedicated infusion suite for research allows us to plan and execute more complex clinical trial protocols that are earlier in a product's development.

While it has been very rewarding to continue to work with the 22 hospital departments who have experience in clinical research, it is also exciting to welcome new departments that are relatively new to research but have the passion to do so. These include the therapeutic areas of mental health, dermatology and orthopaedics. With exposure to digital health and remote monitoring we are ensuring that we are keeping up with the latest developments in health research delivery.

Lastly I'd like to thank our team at MMCT for their professionalism and hard work in an environment that has often at times seemed uncertain. Their dedication to research excellence and the participants involved mean we face the new financial year well equipped to continue to provide world class clinical trials to the people in our community.



**Dr Edward Watson**

CEO



# GENERAL PERFORMANCE

Dashboard FY20

## MMCT Staff

### Total Staff

Total Staff Including Contractors who worked at MMCT during 2020

**43**

### Research Staff

Includes Nurses, Phlebotomists & Statisticians

**31**

### Commercial Trials

Total number of commercial trials underway in 2020

**77**

### Grant Funded Trials

Total number of grant funded /Investigator led trials

**42**

## Trial Metrics

### New Trial Activations

Commercial Trials activated during FY20

**19**

### Commercial Feasibilities

Total feasibilities received during FY20

**188**

### New Trial Participants

new entries into trials 2020

**185**

### Total Participants

includes ongoing multi-year trials

**436**

## Our Revenues

### Total Revenue

**\$5.6m**

### Reserves

**\$5.99m**

### Grant Revenues

Designated/Restricted Reserves Spent During the year

**\$1.2m**

### Reserves Spent

Designated/Restricted Reserves Spent During the year

**10%**

### Hospital Activity

#### Active Departments

Number of Hospital Departments we worked with in 2020

**22**

#### Active Investigators

Number of principal investigators involved in commercial and/or grant trials

**43**

### Trial Activity

#### Commercial Trials by Department

Haematology

**20**

Rheumatology

**14**

Cardiology

**8**

Interventional Radiology

**2**

Clinical Lipidology

**2**

Dermatology

**1**

Gastroenterology

**14**

Diabetes

**8**

Respiratory

**4**

Renal

**2**

Otorhinolaryngology

**1**

Paediatric

**1**

### Visit Activity

#### Visits

Total number of trial visits

**3397**

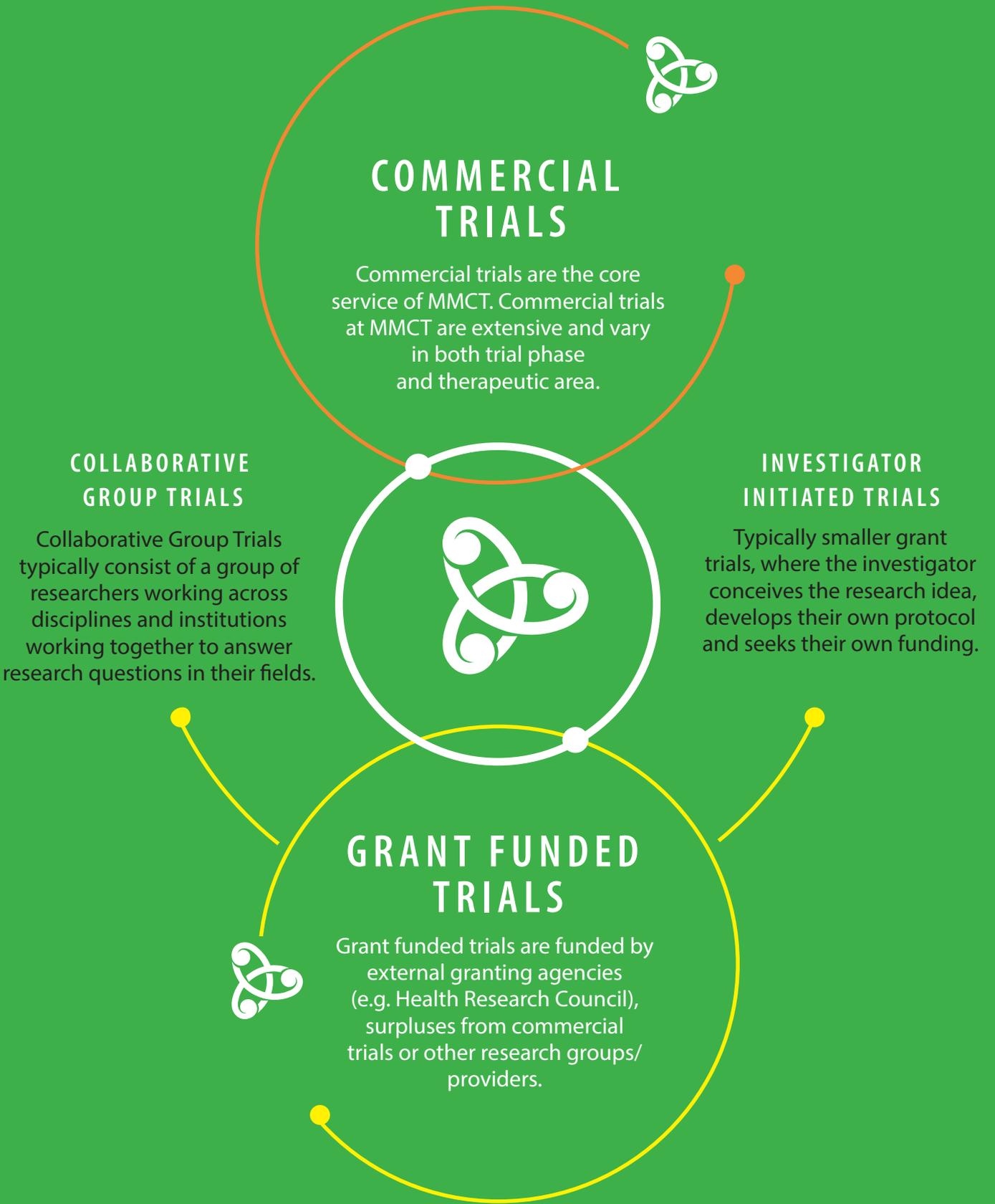
#### Money Saved

Estimated total savings to CM Health

**\$1.0m**

# WHAT WE DO

The types of research we undertake



## COMMERCIAL TRIALS

Commercial trials are the core service of MMCT. Commercial trials at MMCT are extensive and vary in both trial phase and therapeutic area.

## COLLABORATIVE GROUP TRIALS

Collaborative Group Trials typically consist of a group of researchers working across disciplines and institutions working together to answer research questions in their fields.

## INVESTIGATOR INITIATED TRIALS

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

## GRANT FUNDED TRIALS

Grant funded trials are funded by external granting agencies (e.g. Health Research Council), surpluses from commercial trials or other research groups/providers.

# WHAT WE DO

## An overview

### MMCT leads the recruitment of participants into a number of the clinical trials that we participate in.

MMCT has a collaborative team of highly skilled and experienced clinicians, research nurses and support staff. Our flexible work model enables us to double or triple the number of research nurses working on a particular trial during the critical trial enrolment period to ensure we meet recruitment targets.

We also have strong support for research from our local District Health Board, Counties Manukau (CM Health), which serves a population of 560,000 that has a high prevalence of patients with long-term health conditions.

We partner with local Primary Healthcare Organisations (PHOs) who support us to lead recruitment into a number of the clinical trials we undertake.

**MMCT executed 120 clinical trial protocols in FY20. Two thirds of these protocols were commercial trials, sponsored by commercial companies.**

### Our Strengths

**MMCT generates high-quality data for our global partners.**

Our staff manage all aspects of the clinical trials process to ensure:

- Smooth transition through Institutional Review Board (IRB)/Independent Ethics Committee (IEC) processes
- Good Clinical Practice (GCP) compliant processes
- Our internal pharmacy and laboratory ensures fast, efficient services for all trials

**MMCT has the facilities and expertise to undertake all phases (I-IV) of clinical trials**

### Clinical Trial Recruitment Performance FY20

Overall percentage of participants recruited to active trials

**78%**

Overall percentage of active trials that exceeded the recruitment target

**22%**

# WHAT WE DO

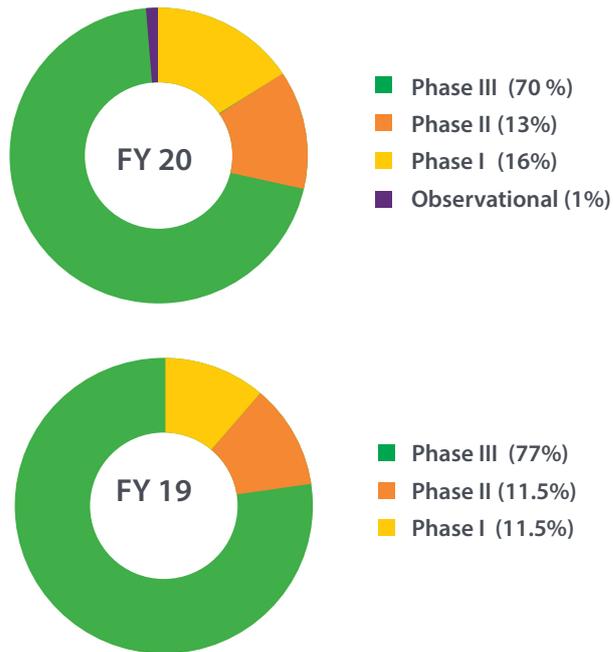
## Commercial Clinical Trials

### MMCT administered 77 commercial trials in FY20.

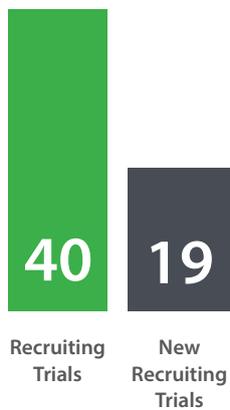
The majority of the commercial trials we managed in FY20 were Phase III drug trials of experimental new medicines. We also conducted a number of device trials predominantly in Cardiology.

We have built our capability and capacity to carry out earlier phase (Phase I and II) trials, which is reflected in the breakdown of our active trials by phase. Early phase trials require considerable medical research experience and sophisticated healthcare systems and infrastructure to make them successful. 29% of our trials in 2020 were Phase I and Phase II trials.

Commercial Trials - by Phase



### Recruiting Trials FY20



### Commercial Trials by Department at CM Health FY20

| Department                | Number of Active trials | Number of Participants* |
|---------------------------|-------------------------|-------------------------|
| Diabetes                  | 8                       | 90                      |
| Cardiology                | 8                       | 80                      |
| Gastroenterology          | 14                      | 71                      |
| Rheumatology              | 14                      | 40                      |
| Renal                     | 2                       | 40                      |
| Respiratory               | 4                       | 39                      |
| Haematology               | 20                      | 35                      |
| Clinical Lipidology       | 2                       | 24                      |
| Radiology                 | 2                       | 5                       |
| Dermatology               | 1                       | 5                       |
| Paediatrics               | 1                       | 4                       |
| Otorhinolaryngology (ENT) | 1                       | 3                       |
| <b>Grand Total</b>        | <b>77</b>               | <b>436</b>              |

\*Number of participants that had visits in FY20

# WHAT WE DO

**FY20 was another active year in grants research. Thirteen departments at Middlemore Hospital engaged in grant funded trials in FY20.**

The majority of grant trials are initiated elsewhere by other New Zealand hospitals, or are collaborative group studies led by research groups from around the world whereas Middlemore Hospital participates as a collaborative site.

Notably, this year, several of our CM Health investigators were successful in their bids for funding from the Health Research Council (HRC) to carry out public-good research trials.

## ASCOT

Dr Susan Morpeth (Clinical Microbiologist and Infectious Diseases Consultant) was awarded funding to run the NZ arm of ASCOT – the Australasian COVID-19 Trial. This is an adaptive platform clinical trial which aims to test potential treatments for COVID-19 among people unwell enough to need admission to hospital, but not so unwell that they need intensive care. The trial will recruit patients across 11 New Zealand hospitals, more than 70 hospitals in Australia, and India will also be a participating country (hospital numbers to be confirmed).

## Grant Funded Research

### SNAP

The SNAP trial funded by a Project Grant, led by Dr Genevieve Walls (Clinical Microbiologist and Infectious Diseases Consultant) is an innovative platform trial to evaluate the impact of a range of interventions to reduce mortality for patients with Staphylococcus aureus bacteraemia (SAB). The outcomes of the trial will address current treatment decisions for which there is clinical uncertainty and hope to update practice and improve outcomes for patients with SAB.

### RESVERATROL

Dr Benjamin Diggins (Respiratory Research Fellow) and Dr Conroy Wong (Respiratory Consultant) were awarded Feasibility Study funding to conduct a trial investigating resveratrol as a potential novel treatment for bronchiectasis. Resveratrol is a naturally occurring antioxidant with anti-inflammatory and antiviral activity found in many foods including red wine, grapes, blueberries, nuts and a variety of other plants. The trial will test whether resveratrol improves key markers of inflammation in patients with bronchiectasis, as well as assess its antimicrobial and antioxidant effects, the optimal dose to use, and the safety of high dose treatment.



Dr Conroy Wong (left), Dr Benjamin Diggins (right)

# WHAT WE DO

## Grant Funded Research (Cont.)

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

#### KISS:

KISS is a multi-centre, phase II, open-label trial measuring dasatinib followed by imatinib in newly diagnosed patients with Chronic Myeloid Leukaemia (CML). The trial is coordinated by Cancer Trials NZ, sponsored by the University of Auckland, and funded by Leukaemia and Blood Cancer NZ. KISS is led by local haematologists; Principal Investigators – Dr Peter Browett (ADHB) and Dr Gordon Royle (CM Health). Findings from this trial will inform improved treatment options for CML patients in New Zealand.

#### REMAP-CAP:

The REMAP-CAP trial is a global collaborative trial with over fifty sites worldwide evaluating interventions for patients with community acquired pneumonia (CAP). It uses a trial design known as a REMAP, a randomised, embedded, multifactorial, adaptive platform trial designed to evaluate a number of treatment options (domains) simultaneously. The adaptive nature of the trial design means that it is able to adjust to an event of research findings and events like pandemics. For example, REMAP-CAP has added COVID-19 domains relevant to the treatment of patient with CAP resulting from Coronavirus. The NZ arm of the trial is sponsored by the Medical Research Institute of New Zealand and is led locally by Dr Alex Kazemi (ICU Consultant).

#### ABC and CHiPS:

ABC, designed and led by Elizabeth Nevill (CM Health Clinical Nurse Specialist), and CHiPS, designed and led by Joanne Clements (CM Health Clinical Nurse Specialist), are nurse led research trials in the neonatal department. Both trials were awarded funding from CM Health Tupu research grants and Fisher and Paykel Healthcare funding. The ABC trial is examining the effects of breathing support during delayed cord clamping for very preterm infants. The CHiPS trial compares the duration and safety of differing weaning strategies for preterm infants needing respiratory support. These research trials were designed to answer local questions relevant to our population and CM Health neonatal unit.

#### Factorial4VLU:

The Factorial4VLU trial is HRC funded. It is a collaborative trial with the National Institute for Health Innovation (NIHI) at the University of Auckland and Auckland DHB. Professor Andrew Jull (UoA) is the Principal Investigator and Trish Johns (Operations Manager – Papakura Home Health Care) is the local investigator at CM Health. The trial aims to evaluate the effectiveness of prescribed exercise programme and/or dilute hypochlorous acid wound solution in comparison to standard care for venous leg ulcer (VLU) healing. The findings from this trial will provide the evidence-based clinical research around effective adjuvants to compression that is currently not available, both regionally and internationally.

### FY20 Grant funded trials - centre of initiation breakdown

| Hospital Department | Initiated CM Health | Initiated elsewhere | Total Grant funded trials |
|---------------------|---------------------|---------------------|---------------------------|
| Cardiology          | -                   | 2                   | 2                         |
| Diabetes            | 1                   | 1                   | 2                         |
| Gastroenterology    | 1                   | 1                   | 2                         |
| Haematology         | -                   | 8                   | 8                         |
| Home Health         | -                   | 1                   | 1                         |
| Infectious Disease  | -                   | 2                   | 2                         |
| Intensive Care      | -                   | 6                   | 6                         |
| Neonatal            | 1                   | 3                   | 4                         |
| Paediatrics         | -                   | 6                   | 6                         |
| Plastics            | 1                   | -                   | 1                         |
| Renal               | 3                   | 2                   | 5                         |
| Respiratory         | 1                   | 1                   | 2                         |
| Womens Health       | -                   | 1                   | 1                         |
| <b>Grand Total</b>  | <b>8</b>            | <b>34</b>           | <b>42</b>                 |



**FY20 was another active year in grants research. Thirteen departments at Middlemore Hospital engaged in grant funded trials in FY20.**

THE GRANTS AND REGULATORY/COMMERCIAL SUPPORT TEAM: Chaewoo Jun, Nicola Jackson, Kate Msiska, Catherine Howie, Renee Railton

# BENEFITS

## to the community

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

These benefits are thought to be a result of the rigorousness of the documented protocol driven care combining with more time available for the patient and the continuity of care with specialist nurses and doctors. Additionally a large benefit of being part of a clinical trial is the learnings patients themselves develop about their disease and what can help. In an on-going survey at MMCT 100% of participants would recommend that other patients be involved in a clinical trial.

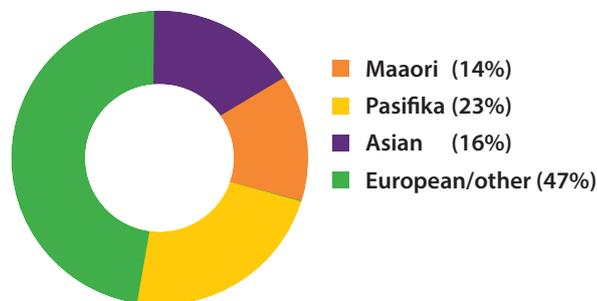
Additionally as New Zealand has a government policy of very tight restrictions to novel medications often the only way patients can access leading edge medical advancements for their disease is through clinical trials.

Such 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. Such staff acknowledge the opportunity to offer their patients more care options and to learn about treatments other than what is standardly available.

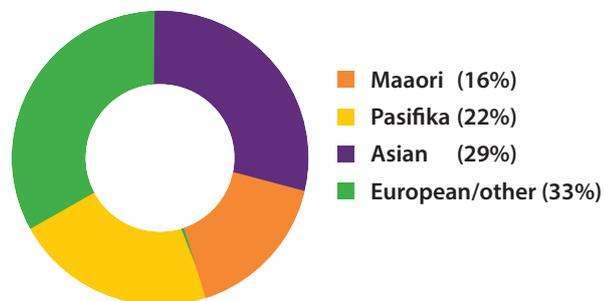
Health inequality is linked to economic and social deprivation. A significant number of our community in Counties Manakau have poorer outcomes than other parts of the country. Clinical trials can add to the potential options for such patients through helping to address some of the barriers to better care.

### The ethnic mix of our trial participants reflect that of the CM Health Resident Population

**2020 Ethnicity Mix of Trial Participants**



**2020 Ethnicity of CM Health Resident Population**



Source: Clinical trial Participation improves outcome: A matched historical cohort study. Baker J et al, Journal of the Society For Clinical Trials 2013;10: 735-743

### Graham Raniera King

*Graham has Type 2 Diabetes*

#### How did you hear about taking part in clinical research?

I was referred to Manukau Superclinic to see Dr John Baker for my diabetes, which is when I heard about the possibility of being on a clinical trial for my diabetes.

#### Could you tell me about your account of being part of clinical research?

My father was a diabetic and he never had great control of his diabetes. He eventually had to go on dialysis, then had a kidney transplant and passed away from complications from that after 12 years. I had seen first-hand my father go through the whole journey so when they asked if I wanted to be a part of research, I had no hesitation. My first trial started in 2015.

My experience of being part of clinical research has been fantastic. Dr John Baker (Clinical Director) is an expert in his field and he is really nice and lovely to deal with. He and Ruth (Cammell) (Research Nurse) must see hundreds of patients but they make me feel like I am their only one. They don't have to but they go out of their way to see me. They treat me like family.

One of the best parts of being on a trial is that I get to see a diabetic specialist. Because I was on the trial, I got access to a modern diabetes drug [dapagliflozin] used in other countries but not funded in New Zealand. By being on the new drug it increased my GP's interest in modern diabetes drugs that they don't normally use here.

#### Would you recommend others to be on a clinical trial?

I would recommend it to others, no hesitation. Research is invaluable. My health wouldn't be as good if I didn't go on a trial, from having poor control of my diabetes to now, a lot better than I used to be. You get to see a specialist and you form a relationship with them. I was born Māori and there are a lot of Māori out there with diabetes. I said yes to research with no hesitation because if my contribution helps even one person out there, it's worth it. And everyone there (at Middlemore Clinical Trials) are all lovely people. You must attract people alike because they are all lovely to deal with.

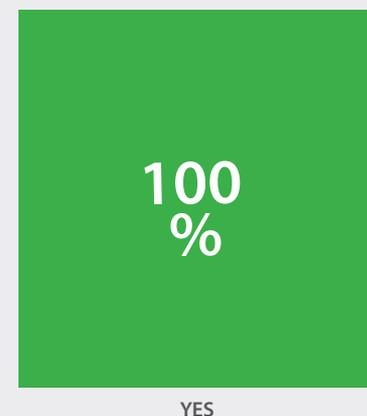


### 2020 Participant Survey The friendliness of our staff to you and your whānau\*



\*Whānau is the Māori name encompassing extended family and an individuals support network. It is widely used in NZ and in the health environment.

### 2020 Participant Survey Would you recommend being involved in clinical research to others?



### Raewyn Straker

*Raewyn has Type 2 Diabetes*

**How did you hear about taking part in clinical research?**

I heard about it through my doctor. I think someone rang me and told me to speak to my doctor about participating, and he recommended that I take part.

**Can you tell me about your account of being part of clinical research?**

I have enjoyed coming here; everyone is nice, lovely and helpful. John Baker and Ruth are really awesome; they're very helpful, nice and encouraging. The best part of taking part in clinical research is that by me participating, I am helping others with diabetes and I like helping people.

**Would you recommend others to be on a clinical trial?**

I would definitely recommend it to others. I'd recommend people to ring up and find out if there is a trial they might be suitable for.



### Jacklyn Thompson

*Jacklyn suffers from a chronic cough.*

**How did you hear about taking part in clinical research?**

I heard about the trial on social media.

**Can you tell me about your account of being part of clinical research?**

I found it really easy, and good. Everything was explained including what was on the forms, there were no hidden secrets. The location (Middlemore Hospital) is very easy to access, and petrol and parking costs get reimbursed when you come in for a visit.

**Would you recommend others to be on a clinical trial?**

I would definitely recommend it to others. The staff here are absolutely wonderful. They make you feel a part of the team; there's nothing to lose and plenty to gain. The best part of taking part is to think that there could be a treatment for chronic cough, which I've had for ten years, and with me participating in the research I could help other people out there with chronic cough.



**2020 Participant Survey**  
Overall Satisfaction with MMCT



**2020 Participant Survey**  
Rate your overall experience in being involved in a clinical trial





Anne Kendall (left) MMCT Research Nurse

## THE INFUSION SUITE

MMCT has recently completed the installation of a bespoke infusion suite that sits within our unit.

The advent of MMCT having its own bespoke clinical trial infusion suite supports MMCT's driving ambition to be world-class.

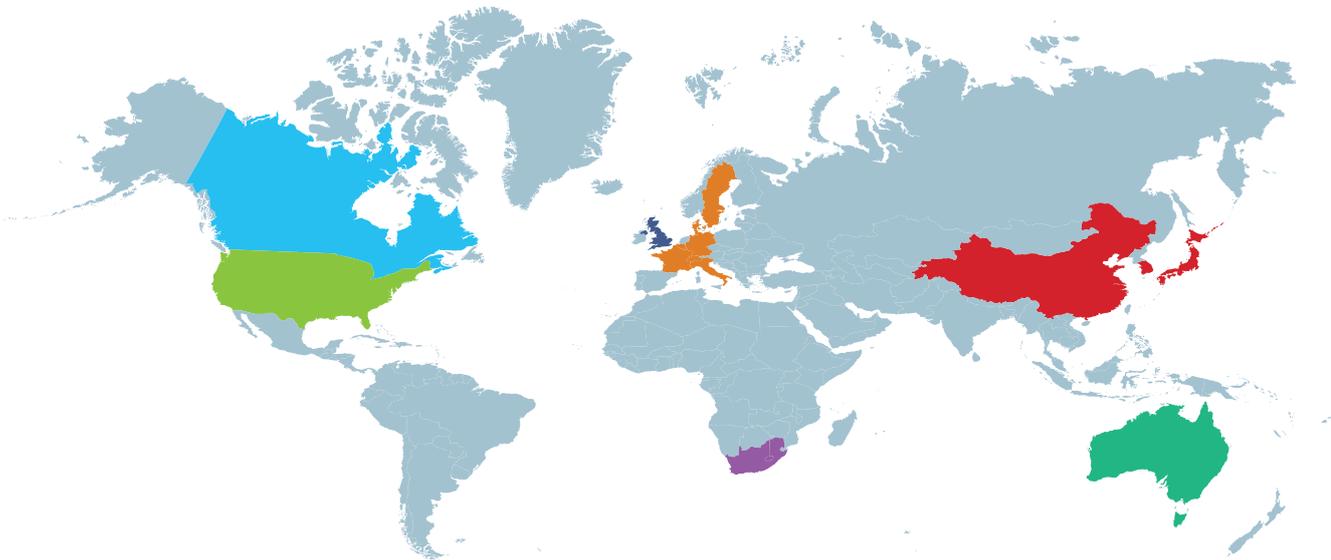
The speciality areas that will likely be involved in infusion trials are:

- Hepatology
- Inflammatory bowel disease
- Rheumatology
- Respiratory
- Cardiovascular
- Autoimmune disorders (e.g Systemic Lupus Erythematosus, Psoriasis)
- Haematology and Oncology

Infusion trials are often earlier phase trials, involving cutting edge technology which makes them attractive to both investigators and potential participants.

# FEASIBILITIES

MMCT works with a global network of trial sponsors



Domiciliary origin of Sponsors that MMCT worked with in FY20

- Canada
- United States
- United Kingdom
- Switzerland
- France
- Belgium
- Sweden
- Germany
- Denmark
- Italy
- South Africa
- China
- South Korea
- Japan
- Australia

Clinical Trial New Feasibilities Received



## New Trial Feasibilities received from 58 unique Sponsors and 21 CROs

### Sponsor

AbbVie  
Molecular Templates  
Merck  
AstraZeneca  
Pfizer  
Roche  
Gilead  
Boehringer Ingelheim  
Sanofi-Aventis  
GlaxoSmithKline  
VIR Biotechnology  
Seres Therapeutics  
Ascendis Pharma Endocrinology Division  
Bayer HealthCare

Connect Biopharmaceuticals  
TigerMed  
Eli Lilly and Company  
MorphoSys  
Enanta Pharmaceuticals  
Rhizen Pharmaceuticals  
Arrowhead Research  
Keros Therapeutics  
Atriva Therapeutics  
Promethera Biosciences  
Ellipses Pharma  
CTI Biopharma  
CSL Behring LLC  
Dr. Reddys Laboratories S.A

Nodthera  
Idorsia Pharmaceuticals  
Pliant Therapeutics  
Eidos Therapeutics  
BeiGene  
Zambon  
Metaventon  
Insmed  
Elixir Medical Corporation  
Scohia Pharma  
Odonate Therapeutics  
Celgene Corporation  
Pharmacyclics  
Terns Pharmaceuticals  
Profusa

Carmot Therapeutics  
Eloxx Pharmaceuticals  
Light AI\*  
BioAegis Therapeutics  
Lyra Therapeutics  
Aligos Therapeutics  
Altum Pharmaceuticals  
K-Group Alpha  
TG Therapeutics  
KoBioLabs  
Kyowa Hakko Kirin Co  
Imago Biosciences  
AATRU Medical  
Immunocore

### CRO

Allergan  
Bionical-Emas  
Clinical Network Service (CNS)  
Covance  
CTI  
George Clinical  
ICON Clinical Research  
Infinity Consulting  
IQVIA (Quintiles)  
Matatika Consulting Aotearoa  
Medpace  
NAMSA  
Novotech  
Novum Pharmaceutical Research Services  
Pacific Clinical Research Group (PCRG)  
PAREXEL International  
Pharmaceutical Solutions  
PPD  
PRA International  
PSI-CRO  
Syneos Health  
Worldwide Clinical Trials (WCT)



## MMCT STAFF

**MMCT's staff are highly experienced research professionals proficient in all aspects of clinical trial management.**

NURSE MANAGERS: Diane Caveney, Sandy McGreevy, Anne Kendall

# AREAS OF RESEARCH

## Activity by department in FY20

### HAEMATOLOGY

#### CLINICAL DIRECTOR

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 the Phase II and III trials provide patients with access to medicines that are otherwise not available in New Zealand, or not available for the indication under investigation.

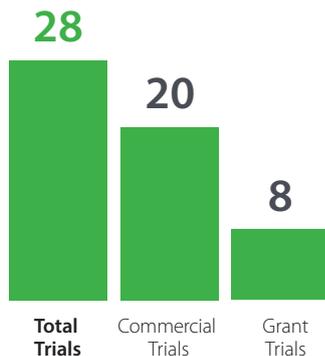
#### RESEARCH TEAMS

##### MMCT

Alice Cassidy (Research Nurse), Chris Giffney (Research Nurse), Anne Kendall (Associate Charge Nurse Manager), Ella Liang (Research Nurse), Katie Seto (Research Nurse), Liz Walker (Research Nurse).

##### CM Health

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



### GASTROENTEROLOGY

#### CLINICAL DIRECTOR

Dr Paul Casey/ Dr Anurag Sekra

The Gastroenterology Department has significantly increased their participation in commercial and grant-funded clinical trials over the past two years. A significant proportion of the research portfolio is currently focused on 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).

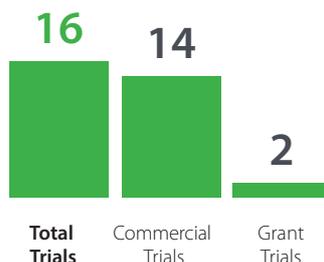
#### RESEARCH TEAMS

##### MMCT

Maryam Apat (Research Nurse), Dr John Baker (Sub-Investigator), Sarah Baresic (Research Nurse), Ruth Cammell (Research Nurse), Jamie Duckworth (Research Nurse), Lauren Fernyhough (Research Nurse), Renate Koops (Sub-Investigator), Johanna van der Kolk (Research Nurse).

##### CM Health

Dr Tien Huey Lim (Investigator),  
Dr Ashok Raj (Investigator),  
Dr Ming Han Lim (Sub-Investigator),  
Dr Henry Wei (Sub-Investigator),  
Dr Ibrahim Hassan (Sub-Investigator),  
Dr Adele Melton (Sub-Investigator).



### RHEUMATOLOGY

#### CLINICAL DIRECTOR

Dr Sunil Kumar

Rheumatology research continues to have the most active trial program in the Auckland region, with a further 5 commercially sponsored clinical trials initiated this year. 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), Sandy McGreevy (Charge Nurse Manager), Cecilia Paul (Research Nurse), Mary Paul (Research Nurse).

##### CM Health

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



## DIABETES

### CLINICAL DIRECTOR

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

Maryam Apat (Research Nurse), Dr John Baker (Investigator), Sarah Baresic (Research Nurse), Ruth Cammell (Research Nurse), Lea Charlesworth (Research Nurse), Jamie Duckworth (Research Nurse), Penelope Eadie (Research Nurse), Lauren Fernyhough (Research Nurse), Susan Ross-Heard (Research Midwife).

#### CM Health

Dr Renate Koops (Investigator), Dr Brandon Orr-Walker (Investigator), Dr John Griffiths (Sub-Investigator), Dr Rinki Murphy (Sub-Investigator), Dr Ian Rosen (Sub-Investigator).

## CARDIOLOGY

### CLINICAL DIRECTOR

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), Diane Caveney (Associate Charge Nurse Manager), Penelope Eadie (Research Nurse), Kavita Gounder (Research Nurse), Lynette Pearce (Research Nurse).

#### 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).

## PAEDIATRICS

### CLINICAL DIRECTOR

Dr Richard Matsas

The Paediatric and Neonatal team has had another outstanding year in research. The department engaged in mostly grant funded trials, as unfortunately the COVID-19 virus meant several commercial infant RSV trials were placed on hold. Research topics in the department reflect the diseases which unfortunately are prevalent in our local community including Respiratory Syncytial Virus (RSV), Bronchiolitis, bronchiectasis, sudden infant death, rheumatic fever, pneumonia, influenza and asthma.

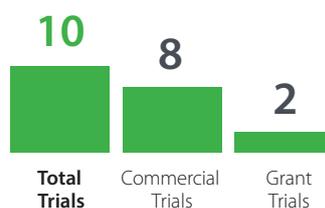
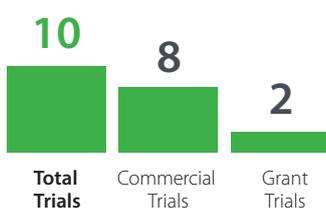
### RESEARCH TEAMS

#### MMCT

Renee Railton (research manager – grants)

#### CM Health

Dr Christine McIntosh (Investigator), Dr Mike Meyer (Investigator), Dr Jocelyn Neutze (Investigator), Dr Adrian Trenholme (Investigator), Dr Rachel Webb (Investigator), Renee Clark (Research Nurse), Shirley Lawrence (Research Charge Nurse), Maricar Santiago Maminta (Research Nurse), Mandy Retter (Research Nurse).



# AREAS OF RESEARCH

## Activity by department in FY20

### RENAL

#### CLINICAL DIRECTOR

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 kidney disease and haemo- and peritoneal dialysis

#### RESEARCH TEAMS

##### MMCT

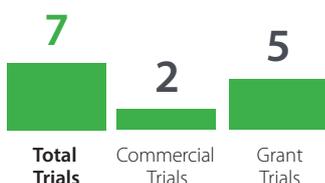
Lea Charlesworth (Research Nurse),  
Jamie Duckworth (Research Nurse),  
Penelope Eadie (Research Nurse),  
Brenda Luey (Research Nurse).

##### CM Health

Dr Christopher Hood (Investigator),  
Dr Jamie Kendrick-Jones (Investigator),  
Dr Mark Marshall (Investigator),  
Dr Rachel Walker (Investigator),  
Dr Noella Ahn (Sub-Investigator)  
Dr Jonathan Hsiao (Sub-Investigator),  
Dr Michael Lam (Sub-Investigator),  
Dr Daniel Lin (Sub-Investigator),  
Dr Elene Ly (Sub-Investigator),  
Dr Budhun Palouse (Sub-Investigator),  
Dr Tina Sun (Sub-Investigator),  
Dr Hari Talreja (Sub-Investigator),  
Dr Hla Thein (Sub-Investigator),  
Dr Villiami Tutone (Sub-Investigator).

### Departments at CM Health Engaged in Research with MMCT in FY20

| Department                | Commercial Trials | Grant Trials | Total Trials |
|---------------------------|-------------------|--------------|--------------|
| Haematology               | 20                | 8            | 28           |
| Gastroenterology          | 14                | 2            | 16           |
| Rheumatology              | 14                |              | 14           |
| Diabetes                  | 8                 | 2            | 10           |
| Cardiology                | 8                 | 2            | 10           |
| Paediatrics               | 1                 | 6            | 7            |
| Renal                     | 2                 | 5            | 7            |
| Respiratory               | 4                 | 2            | 6            |
| Intensive Care            |                   | 6            | 6            |
| Neonatal                  |                   | 4            | 4            |
| Infectious Disease        |                   | 2            | 2            |
| Clinical Lipidology       | 2                 |              | 2            |
| Radiology                 | 2                 |              | 2            |
| Dermatology               | 1                 |              | 1            |
| Otorhinolaryngology (ENT) | 1                 |              | 1            |
| Womens Health             |                   | 1            | 1            |
| Home Health               |                   | 1            | 1            |
| Plastic Surgery           |                   | 1            | 1            |
| <b>Grand Total</b>        | <b>77</b>         | <b>42</b>    | <b>119</b>   |



25 MMCT Research Nurses  
and 43 Principal Investigators  
engaged in Clinical Research  
FY20

# AREAS OF RESEARCH

## New departments we are engaging with

(Shown in no particular order)

### MENTAL HEALTH

#### CLINICAL DIRECTOR

Dr Ian Soosay

The Mental Health team is keen to increase research activities in the coming year, focusing on clinical trials for mobile health applications. The aim is to provide evidence based research outcomes that enable decision making regarding access and support in the provision of mental health services. Based on prevalence data, it is expected that over 20% of CM Health's population have a mental illness that warrants some degree of intervention. Dr Nicola Jackson (Senior Grants and Regulatory Associate) is working closely with the Mental Health Department.

### ORTHOPAEDIC SERVICES and the Auckland Spinal Rehabilitation unit

#### CLINICAL DIRECTOR

Dr Rodney Gordon

Dr Alpesh Patel, Dr Betsy Mathew and Dr Simon Manners engaged with MMCT in order to support the establishment of a Spinal Cord Injury Clinical Research Unit in Auckland. The unit aims to conduct translational research in the field of spinal cord injury. The researchers also aim to create a registry for Cervical Spondylotic Myelopathy (CSM) and have a number of research projects in set-up scheduled to begin in 2021.



Dr Alpesh Patel (left)  
Dr Simon Manners (right)

### DERMATOLOGY

#### CLINICAL DIRECTOR

Dr Paul Jarrett

Dr Paul Jarrett is working closely with MMCT to set up further commercial trials in atopic dermatitis and other dermatological conditions which will enable access to medicines that otherwise are not available in New Zealand.



Dr Paul Jarrett

# SPOTLIGHT ON GASTROENTEROLOGY

Worldwide there are about 300 million people living with undiagnosed viral hepatitis .

Unless detected and treated, viral hepatitis can cause hepatocellular carcinoma (liver cancer) and cirrhosis (scarring of the liver). As part of the global effort towards finding the cure for hepatitis B, the gastroenterology research team including Dr Tien Huey Lim works on several clinical trials investigating potentially curative treatments for hepatitis B. Dr Lim also is running Non-Alcoholic SteatoHepatitis (NASH) trials investigating treatments to reverse cirrhosis caused by the inflammation of the liver.

Dr Ashok Raj leads the inflammatory bowel disease trials (Ulcerative Colitis and Crohn's Disease).

**In FY20, MMCT managed 16 gastroenterology trials at Middlemore, with 71 participants.**



Dr Ibrahim Hassan, Dr Tien Huey Lim, Dr Ashok Raj

## Dr Tien Huey Lim – Principal Investigator (Gastroenterology)

There are two main liver problems in the world today – Hepatitis B Virus (HBV) and Non-Alcoholic SteatoHepatitis (NASH). In the case of HBV, we have antiviral medications to control the virus but patients have to take the medication for the rest of their life. The cure rate for hepatitis B infection for patients on antiviral medication is less than 3%. As patients with chronic hepatitis B infection (CHB) get older, the risk of developing liver cancer increases, and the risk increases each year they are infected. Hence there is a need to try and find curative treatments to cure hepatitis B completely.

Hepatitis B is most prevalent among the Asian, Maaori and Pasifika populations (the prevalence of hepatitis B is 7-8% in the Asian, Maaori and Pasifika population, in comparison to 1% in the Caucasian population). This means that because of the ethnic diversity in our local community, we have significant numbers of patients with HBV.

We have had a busy year administering six Phase I trials and two Phase II trials in hepatitis B. The curative treatment trials for hepatitis B are designed around the new knowledge gained from the hepatitis C cure. Previously the treatment for Hepatitis C was pegylated interferon (IFN); an injection administered once a week, with oral tablets for a year (48-week treatment). The treatment success rate (or cure rate) under

that year-long treatment was 40%. Now, the treatment is 8-weeks of oral tablets – direct acting antiviral (DAA) – which specifically targets the hepatitis C virus. The cure rate of this treatment is 97%.

The Phase II trials starting in hepatitis B are all looking at combination treatments, centred on sequencing and targeting the virus much better. It is really exciting, but we don't yet know which combination will be successful. We will continue to perform the trials until there is a cure found for HBV.

The second area of huge unmet need is Non-Alcoholic SteatoHepatitis (NASH) – essentially fatty liver. The inflammation of the liver leads to damage / scarring (cirrhosis), eventually to a point where the patient needs to get a liver transplant. In the modern world, where obesity is an issue, the prevalence of NASH continues to increase and so does the need for liver transplants, which is a significant problem for our health system. Fatty liver is now the most common reason for a liver transplant. It has surpassed the number of liver transplants needed because of viral hepatitis, as we have treatments to suppress the virus so that the liver no longer becomes cirrhotic or the rate of cirrhosis is slowed.

Unfortunately the only successful treatment for NASH at the moment is weight loss. If a patient loses more than ten percent of their body weight the NASH essentially goes away, but this is incredibly difficult for

many people we see in clinics. Hence there is a need to find alternative treatments to help patients control their fatty liver, reverse the scarring, and prevent further cirrhosis. The NASH trials we are involved in at the moment are Phase 3, but we see trials come through that are Phase 1b or 2. All these trials aim to reverse the cirrhosis.

## MMCT received 23 new trial enquiries in Gastroenterology in FY20

### Gastroenterology Research at CM Health

- Over the years we have seen new treatments develop through clinical research that completely change the standard of care (e.g. hepatitis C). As researchers we are constantly trying to improve the situation for patients and treatment options we are able to offer. If we can find a cure for Hepatitis B it will reduce the risk of liver cancer in CHB patients by 90% so that's where the drive comes from.
- One of the key philosophies of the department is to try to embed research as part of standard practice. With the recently appointed Clinical Director –

Dr Anurag Sekra and Research Fellow – Dr Ibrahim Hassan, there is large support for clinical research from the department. Research enables clinicians to be knowledgeable on the latest treatment options in development, improving quality and delivery of care.

- Research enables us to collaborate with other prominent names in the field from around the world to stay at the forefront of new developments / innovations. For example, we are taking part in the TAF Breastmilk Study, which is a collaborative group study with Auckland City Hospital and Liverpool Hospital in Sydney (Lead site).
- 25% of the Gastro research fellow's salary is covered by the Gastroenterology research fund, which grows through participating in commercial trials. These funds can be used to develop more research, such as the TAF Breastmilk and Stop Nuc trials (Dr Tien Huey Lim), and upcoming research projects of the human microbiome (Dr Ashok Raj).

### Dr Ashok Raj – Principal Investigator (Gastroenterology)

Inflammatory bowel disease (IBD) is the ongoing inflammation of all or part of the digestive tract. The most common types of IBD are Crohn’s disease and ulcerative colitis. They affect approximately 20,000 New Zealanders, which is amongst the highest prevalence in the world. Standard options for therapy are not particularly appealing for patients as it involves heavily suppressing the immune system (which can cause a number of side effects). Clinical trials offer alternative options of potential treatment for patients with IBD who have maxed out their options for existing therapy. As a clinician, the benefit of offering clinical trials to patients is that it enables patients to access medications that are often available overseas but not yet approved or publically funded in NZ.

Dr Raj’s area of research interest is in the microbiome. To this day, the cause of IBD is unknown. However, IBD was the one of the first GI diseases for which it has been shown that there are abnormal changes (dysbiosis) in the gut microbiome. Newer trials, such as the ulcerative colitis trial we are starting late 2020 are looking at modulating the microbiome rather than suppression of the immune system. Research suggests that the microbiome is linked to mucosal and organ inflammation, which is characterised in many diseases, not just in IBD.

Given the evidence for the involvement of the microbiome in several diseases, it is imperative that we conduct translational research of the microbiome in an array of conditions. Dr Raj is currently collaborating with the Liggins Institute and School of Biological Sciences at the University of Auckland to develop mechanisms to conduct translational research of the microbiome, in partnership with CM Health and Middlemore Clinical Trials.

### Gastroenterology trials administered FY20

| Indication                    | Phase I | Phase II | Phase III | Phase N/A* | Total Trials |
|-------------------------------|---------|----------|-----------|------------|--------------|
| Hepatitis B                   | 6       | 2        | 0         | 2          | 10           |
| Non-Alcoholic SteatoHepatitis | 0       | 0        | 3         | 0          | 3            |
| Ulcerative Colitis            | 0       | 0        | 1         | 0          | 1            |
| Crohn’s Disease               | 0       | 0        | 2         | 0          | 2            |
| <b>Grand Total</b>            |         |          |           |            | <b>16</b>    |

\*Not Applicable - Grant Trials

One of the key philosophies of the department is to embed research as part of standard practice.

Microbiome is the genetic material of all the microbes (bacteria, fungi, protozoa and viruses) that live on and inside the human body.



## GASTROENTEROLOGY

**In FY20 MMCT had 10 hepatitis trials in progress as we joined the global research network's quest to find a cure for Hepatitis B**

MMCT RESEARCH NURSES (GASTROENTEROLOGY) Maryam Apat, Sarah Baresic, Lauren Fernyhough (standing), Johanna van der Kolk (seated), Jamie Duckwork (standing), Ruth Cammell

**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. As at 30 June 2020, commercial/grant trials in progress show an aggregate net surplus of \$1.32 million (30 June 2019 \$1.84 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 2020, total designated/ restricted reserves were \$5.99 million (30 June 2019, \$4.79 million).

### Departmental Breakdown of Granting from Designated/Restricted Reserves

| Department                                | Opening Balance<br>01-Jul-19 | Granting in<br>FY20 | Percent of Grants<br>Used | Closing Balance<br>30-Jun-20 |
|---|------------------------------|---------------------|---------------------------|------------------------------|
| Cardiology & Capex - Restricted           | \$1,423,488                  | \$34,928            | 2%                        | \$1,375,087                  |
| Cardiology - Designated                   | \$286,440                    |                     |                           | \$355,555                    |
| Cardiology - Catheter Lab Nurse Education | \$19,030                     |                     |                           | \$19,321                     |
| Kidz First                                | \$295,618                    | \$277,874           | 94%                       | \$1,291,730                  |
| Haematology                               | \$861,014                    | \$3,721             | 0%                        | \$879,683                    |
| Respiratory                               | \$567,690                    | \$6,262             | 1%                        | \$660,515                    |
| Intensive Care Unit                       | \$395,788                    | \$16,853            | 4%                        | \$403,428                    |
| Rheumatology                              | \$144,452                    | \$25,515            | 18%                       | \$240,430                    |
| Hand / Upper Limb                         | \$165,799                    | \$46,720            | 28%                       | \$162,105                    |
| Renal                                     | \$153,225                    | \$28,160            | 18%                       | \$127,298                    |
| Gastro                                    | \$119,948                    | \$23,014            | 19%                       | \$100,713                    |
| Infectious Diseases                       | \$95,045                     |                     |                           | \$96,495                     |
| Diabetes                                  | \$52,835                     |                     |                           | \$60,014                     |
| Stroke Outcomes                           | \$50,155                     |                     |                           | \$50,920                     |
| Emergency Care                            | \$48,605                     |                     |                           | \$48,984                     |
| Neonatal                                  | \$31,208                     | \$15,648            | 50%                       | \$31,510                     |
| Spinal Unit                               | \$23,953                     |                     |                           | \$24,319                     |
| Home Health                               | \$27,647                     |                     |                           | \$20,334                     |
| Dermatology                               | \$18,180                     |                     |                           | \$19,957                     |
| <b>Total</b>                              | <b>\$4,780,121</b>           | <b>\$478,694</b>    | <b>10%</b>                | <b>\$5,968,397</b>           |

In the year ending June 2020 eight 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.

### Granting spend summary from Designated/Restricted Reserves in FY20

| Spend FY20          | \$      |
|---------------------|---------|
| Research Fellow     | 188,773 |
| Research Nurse      | 192,666 |
| Conferences/Seminar | 31,774  |
| Publications        | 4,178   |

### Granting spend from General Reserves in FY20

| Spend FY20                            | \$     |
|---------------------------------------|--------|
| Research personnel                    | 38,852 |
| Scholarships / Bursaries              | 20,000 |
| Diabetes in Pregnancy registry (DiPR) | 29,064 |
| Training / Sponsorships / Donations   | 2,350  |

### General Reserves

As at 30 June 2020, total general reserves were \$1.08 million (30 June 2019, \$1.44 million).

### Scholarships/Bursaries

In 2020, MMCT provided partial funding for a PhD student stipend of \$25,000 to support the analysis of departmental data on plunging ranular (a rare condition that is especially common in Maori and Pasifika) and the management of obstructive salivary gland disease using a sialendoscopy.

### Diabetes in Pregnancy Registry (DiPR)

The Freemasons Foundation donated \$105,832 to support the establishment of the program in 2016 and a further grant of \$41,916 in November 2017. 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 Audit of primary care Support Service Audit of Primary care. Initially the program involved a 1-year pilot study and collection of retrospective data. This work has been recognised by the Health & Disability Ethics Committee:

“As the research has shown that it is important and worthwhile, the registry should continue to be used as part of standard of care.”

The registry now forms a critical service (funded by CM Health) to support pregnant women with Type II diabetes and enables the support, delivery and evaluation of interventions to prevent and manage Type II diabetes effectively.

### Adolescent Bariatric Surgery study

The Potter Masonic Trust and Perpetual Guardian donated \$92,539 to support this locally designed pilot study designed to evaluate the benefit of intensive lifestyle intervention (low calorie diet and exercise) with or without bariatric surgery for adolescents with morbid obesity, who are at high risk of developing or currently have Type II diabetes. Dr Brandon Orr Walker and Mr Richard Babor are co-Principal Investigators and Dr John Baker is a sub Investigator. The trial is being conducted in partnership with CM Health.

**As at 30 June 2020, total general reserves were \$1.08 million (30 June 2019, \$1.44 million).**

- 1 **Bromberg, J. E. C., S. Issa, K. Bakunina, M. C. Minnema, T. Seute, M. Durian, G. Cull, H. C. Schouten, W. B. C. Stevens, J. M. Zijlstra, J. W. Baars, M. Nijland, K. D. Mason, A. Beeker, M. J. van den Bent, M. Beijert, M. Gonzales, D. de Jong and J. K. Doorduyn (2019).** "Rituximab in patients with primary CNS lymphoma (HOVON 105/ALLG NHL 24): a randomised, open-label, phase 3 intergroup study." *Lancet Oncol* 20(2): 216-228.
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- 5 **Dissanayake, A., A. C. Vandal, V. Boyle, D. Park, B. Milne, R. Grech and A. Ng (2020).** "Does intensive glycaemic control promote healing in diabetic foot ulcers? - a feasibility study." *BMJ Open* 10(1): e029009.
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- 8 **Galante, L., Reynolds, C. M., Milan, A. M., Alexander, T., Bloomfield, F. H., Cameron-Smith, D., ... & Vickers, M. H. (2020).** "Preterm human milk: associations between perinatal factors and hormone concentrations throughout lactation." *Pediatr Res* Jul 29. doi: 10.1038/s41390-020-1069-1. Online ahead of print.
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