

Capabilities Overview



About us

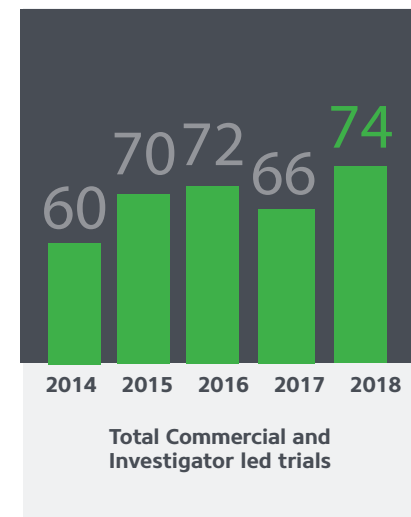
Middlemore Clinical Trials (MMCT) is considered one of the leading commercial clinical trial sites in Australasia.

MMCT leads the recruitment of participants into most of the clinical trials that we participate in and we pride ourselves on generating high-quality data for sponsors.

MMCT is successful because:

- We are aligned to a District Health Board, Counties Manukau Health, catering for a population that has a high prevalence of long term health conditions;
- We have access to databases that allow us to identify potential participants;
- There is a willingness from our local population to participate in clinical trials;
- MMCT enjoys strong support from the local District Health Board, Counties Manukau Health.

**Clinical Trials Per Annum
2014 -2018**





Contents

About Us	2
Location Benefits	4
Areas of Interest	7
Core Competencies	11
Site Facilities	15
Benefits	19

Location Benefits

Located within the campus of Middlemore Hospital, MMCT operates completely independently.

Located at one of New Zealand's largest hospitals, MMCT is in close proximity to a diverse multi-ethnic and low socio-economic population, which provides ready access to good quality trial participants. MMCT operates in a large patient catchment zone with multiple out-patient and community clinics. These cater to the needs of maternity, paediatric, the elderly, middle class and low socio-economic groups. A key benefit of being located at Middlemore Hospital is access to both senior medical personnel and the facilities of a large hospital.

Location Statistics

Counties Manukau Health

Outpatients per annum	450,000
Inpatients per annum	91,000
Hospital staff numbers	4,700
MMCT staff numbers	42

Population Snap Shot



569,400
people live in the region



205,000
live in socio economically
deprived areas



67,280
are over 65



123,500
are children



16% Māori
18% Pacific
10% Asian
42% NZ European





Areas of Interest

MMCT is a world class research centre with proven capabilities over multiple research areas and multiple phases

MMCT seeks to accommodate the worlds best clinical trials that match our most experienced investigators. Our belief is that our trials should provide benefit to the local Counties Manukau population.

In addition to pharmaceutical trials MMCT is an experienced clinical trials and testing partner for medical devices across a broad range of applications, including electronics, software and orthopedics.

Research areas of interest & department team leaders

Paediatrics led by Dr Adrian Trenholme

Haematology led by Dr Sharon Jackson

Diabetes led by Dr Brandon Orr-Walker

Rheumatology led by Dr Sunil Kumar

Renal led by Dr Christopher Hood

Gastroenterology & Hepatology led by Dr Paul Casey

Cardiology led by Dr Selwyn Wong

Respiratory led by Dr Conroy Wong

Dermatology led by Dr Paul Jarrett

Nutritional Studies led by Alayne Healy

Medicine led by Dr Carl Eagleton

ICU led by Dr Alex Kazemi

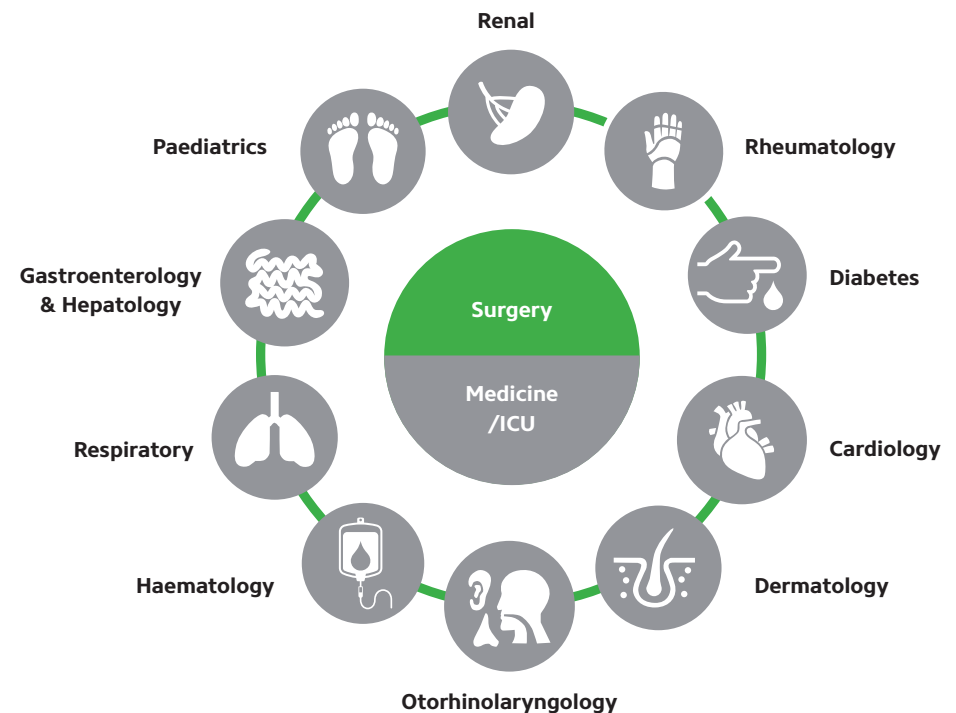
Orthopedics led by Dr Matthew Tomlinson

Otorhinolaryngology led by Professor Randall Morton

Womans Studies led by Dr Sarah Tout

MMCT undertakes all phases of clinical trials
including medical device trials

MMCT enjoys excellent collaboration and
trial activity over a wide range of research areas





Medical Device Testing

Case Study

ASCEND D

For Renal Patients

The ASCEND D clinical trial was a Phase III trial that consisted of adults who had anaemia associated with chronic kidney disease and were on dialysis.

Participant Target - 30

Trial synopsis

The study medication is a tablet that is given daily to safely boost the production of the hormone erythropoietin (EPO), which increases Red Blood Cell production when compared to an approved anaemia treatment.

The Kidney produces EPO which aids in the production of red blood cells, however, in CKD the kidneys are damaged or diseased this making EPO production insufficient.

Red Blood Cells carry oxygen for the body, and anaemia causes fatigue which impacts on the quality of life of the patient.

This trial looked at supporting the production of Red Blood Cells via an oral tablet instead of injections as currently used.

Trial Outcomes

Participant recruiting numbers

Consented 57. Randomised 30. 100% recruited.
One of the highest numbers recruited in Australasia.

The secret to MMCT's success?

Engaged, proactive, enthusiastic and respected PI, with support of engaged sub investigator and Renal Department. Plus excellent co-ordination between multiple renal dialysis units.

What were the highlights?

Participants took tablets over injection, the engagement of a PI and team with Middlemore Hospital, an unmet need and question being answered, increased health literature for participants, excellent patient compliance.

Core Competencies

MMCT is an established, multi-disciplinary clinical trials site that operates to the highest international quality standards. MMCT has a collaborative team of skilled and experienced Principal Investigators (PI's), clinicians, research nurses and support staff. The convenient location on the campus of Middlemore Hospital means MMCT has ready access to multiple departments and specialist health professionals in a wide range of clinical specialties.



ECG monitoring

Core Competencies

Trial Initiation & Approvals

MMCT has clear metrics and key performance indicators when performing a clinical trial. The KPI's are designed to be in alignment with our industry partners to ensure expectations are met. MMCT also facilitates locality and ethics approvals, including a review by Māori (representatives of the local indigenous community).

Participant Recruitment

MMCT's focus and motivation to achieve and succeed in participant recruitment and retention sets the gold standard. We consistently achieve recruitment and retention targets across all specialty (or therapeutic) areas year in and year out.

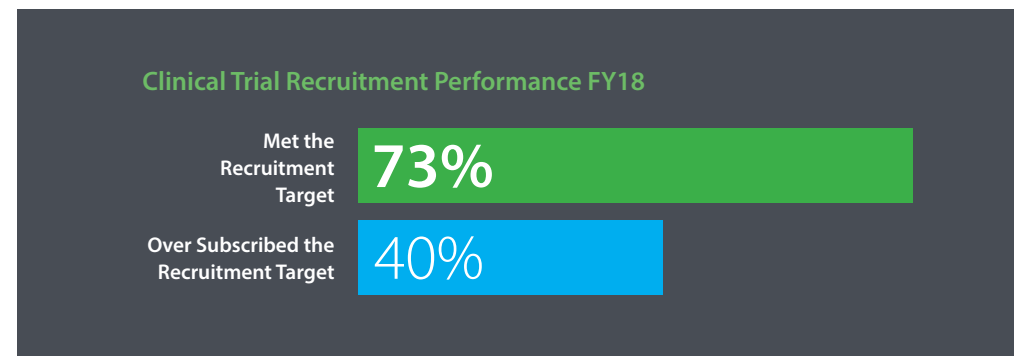
Successful participant recruitment and retention is in part due to how well the clinical trial site engages and communicates with Principal Investigators, the wider hospital, and community health care teams. The inclusion and investment from these skilled people is critical to our trial outcomes and overall satisfaction of participants and the trial teams.

Trial Management

All clinical trials conducted by MMCT have documented reporting processes supported by comprehensive Standard Operating Procedures. Using sophisticated trial management systems, MMCT ensures that all events are tracked and all safety and data reports are produced in line with sponsor's requirements. This is also true for grant trials where provision is made for independent monitoring of the trial and, where appropriate, independent data safety monitoring.

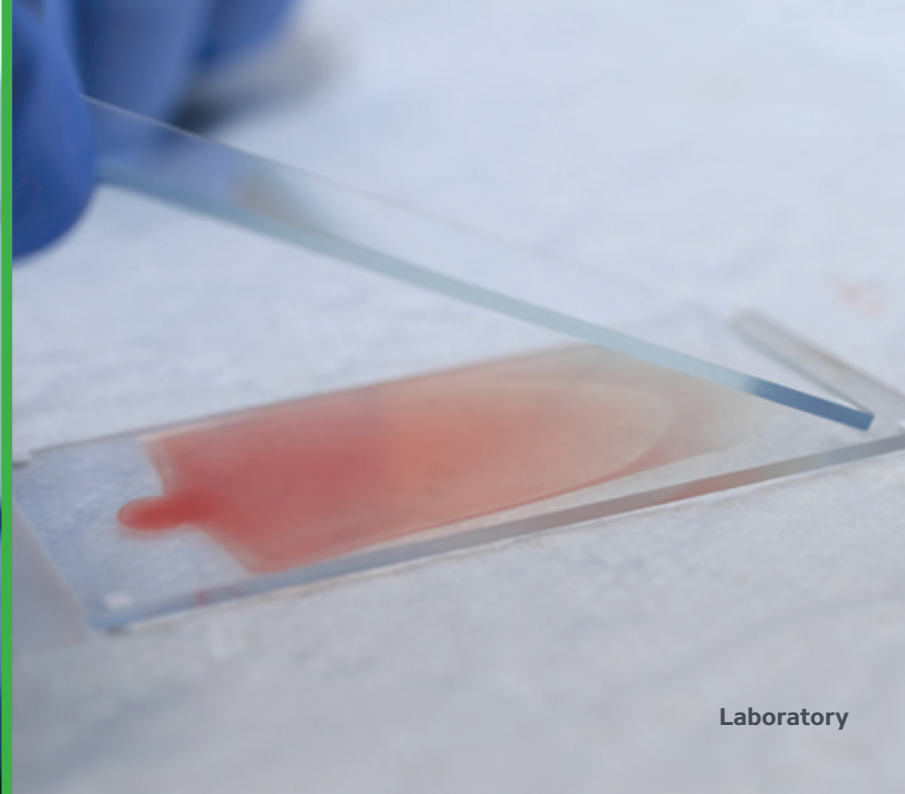
Quality Outputs

MMCT's dedicated Research Nurses ensure that the process of transcription, from source documents to sponsor's Electronic Data Capture (EDC), are clear, transparent and accurate. For all trials MMCT takes pride in ensuring a supply of high quality clean data.





Centrifuges



Laboratory



Transportation Systems



Pharmacy

Site Facilities

MMCT is a full service trial site led by an experienced senior management team of experts and administrators. MMCT has a full suite of modern facilities, including a fully equipped on-site pharmacy and laboratory, temperature controlled investigational product cabinets, as well as adjacent clinic rooms. Nearby hospital services include Middlemore Hospital itself, Kidz First Children's Hospital, Manukau Surgery Centre, mental health, assessment and rehabilitation units.

MMCT's quality site facilities are enhanced by nearby hospital resources.

Site Facilities

MMCT's facilities are of the highest standard, this combined with its convenient location on the Middlemore Hospital campus makes it an attractive place to do trials.



On-site Equipment

- Phlebotomy
- Spirometry
- Fibroscan
- ECG
- Point of care DCA machine for HBA1C
- Resuscitation trolley

On-site Laboratory

- Secure access laboratory
- Minus 80 degree C freezers
- Minus 30 degree C freezer
- Refrigerated centrifuges
- Ambient temperature incubator

On-site Pharmacy

- Pharmacist
- Secure access pharmacy
- Secure Investigational Product cabinets
- Temperature controlled product cabinets
- 24/7 temperature monitoring
- 5 monitored fridges
- Backup power supply



Spirometry



Blood Pressure



Fibroscan



Phlebotomy

KEY BENEFITS

Location

Based at
Middlemore Hospital

Proven Recruiters

Consistently meet
enrolment targets

Resources & facilities

Excellent site
facilities

Excellent Data

Clean data delivered
to sponsors

Benefits

The key benefits include our experience, and the ability to complete clinical trials of all types and sizes. Speed of trial activation, and our access to world class health care professionals at one of New Zealand's leading general, specialist and tertiary hospitals.

Sponsors who work with MMCT are always impressed by the site's speed to trial activation, experience and the quality of data we supply

MMCT offers true world-class clinical trials in New Zealand.

Contact details

CEO
CLINICAL DIRECTOR
CHARGE NURSE MANAGER -RESEARCH

Dr Edward Watson
Dr John Baker
Sandy McGreevy

email: Edward.Watson@mmclintrials.nz
email: John.Baker@mmclintrials.nz
email: Sandy.McGreevy@mmclintrials.nz

Middlemore
Clinical Trials
Future of healthcare



Ph +64 9 270 9758 www.middlemoretrials.nz