

Capabilities Overview



Te Kohinga Ora

*Middlemore
Clinical Trials*



Auckland, New Zealand

About us

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

We are a fully integrated specialist clinical trial unit based at one of New Zealand's largest hospitals - Middlemore Hospital.

At MMCT we believe better health outcomes are achieved through clinical research.

Our strengths:

- highly trained and experienced research staff
- we have the facilities to conduct all phases of clinical trials
- aligned with our local hospitals and primary care networks allowing us to meet our recruitment targets
- the catchment population are willing to partake in clinical trials
- streamlined site activation process resulting in faster First Patient In (FPI)



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Location Benefits

MMCT is well located

MMCT operates in partnership with Counties Manukau Health, and is located within the campus of a large tertiary hospital in South Auckland. Middlemore Hospital serves a culturally diverse resident population of approximately 600,000. A significant proportion of the population suffer from long-term health conditions.

MMCT is one of the largest specialist clinical research units in New Zealand and every year MMCT manages trials across 22 hospital departments.

Location Statistics

Population

Counties Manukau Region (2021) 578,650

Counties Manukau Health

Outpatients per annum 500,000

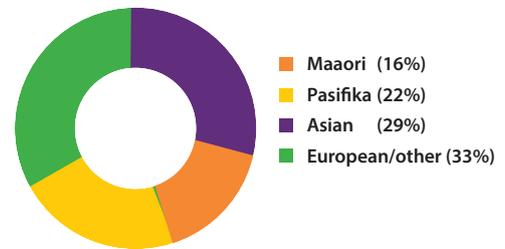
Inpatients per annum 94,000

Hospital staff numbers 4,700

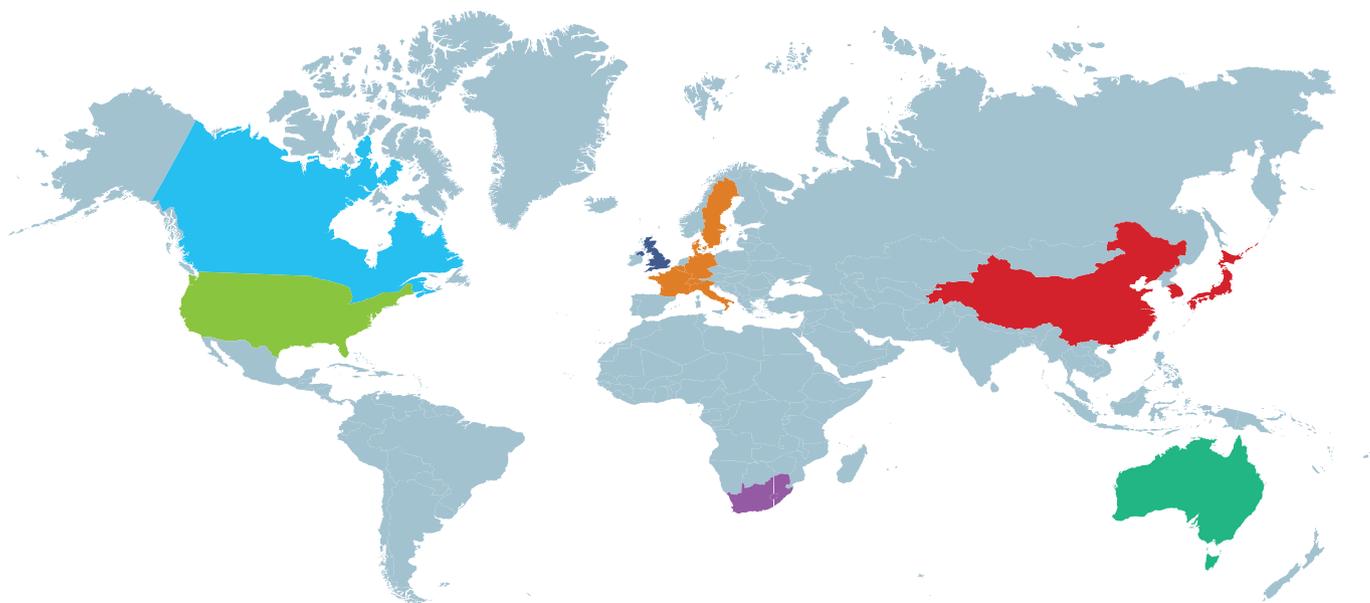
MMCT staff numbers 41

Population Snap Shot

2020 Ethnicity of CM Health Resident Population



MMCT works with an extensive global network of trial sponsors and CROs



MMCT reach over a typical year

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

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. MMCT has ready access to multiple hospital departments and specialist health professionals in a wide range of clinical specialties.

Fast trial activation

MMCT has dedicated regulatory, contracts, budget, and operations personnel to ensure timely start up of trials. In most cases trial activation can be achieved within 90 days of site selection.

Recruitment to target

Our flexible work model enables us to ensure the appropriate number of study coordinators work on a particular trial during the critical trial enrollment period so we meet recruitment targets.

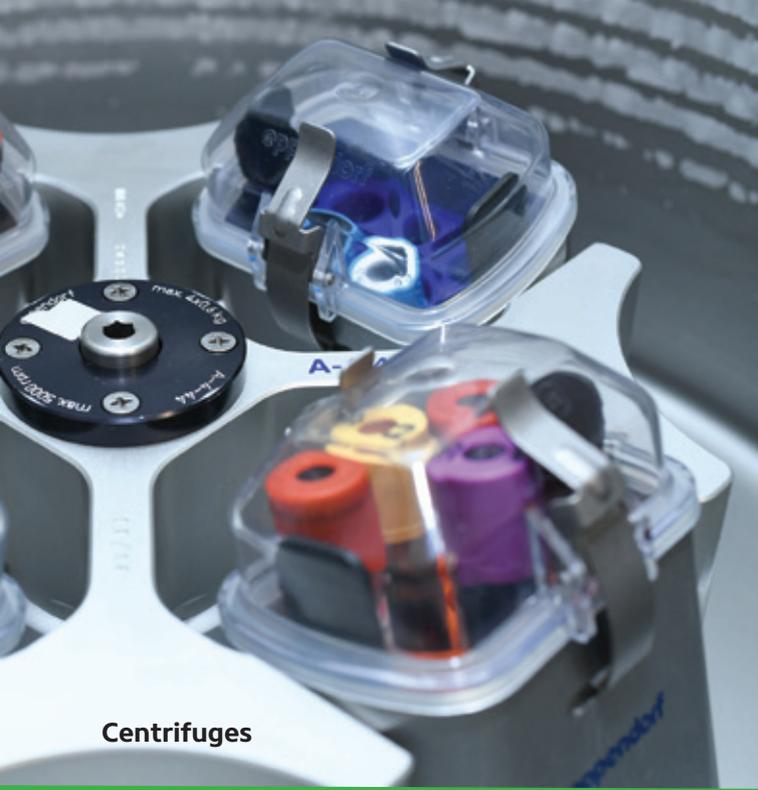
We work in partnership with Primary Health Organisations, Middlemore Hospital departments, and nearby District Health Boards to maximise recruitment.

Trial management

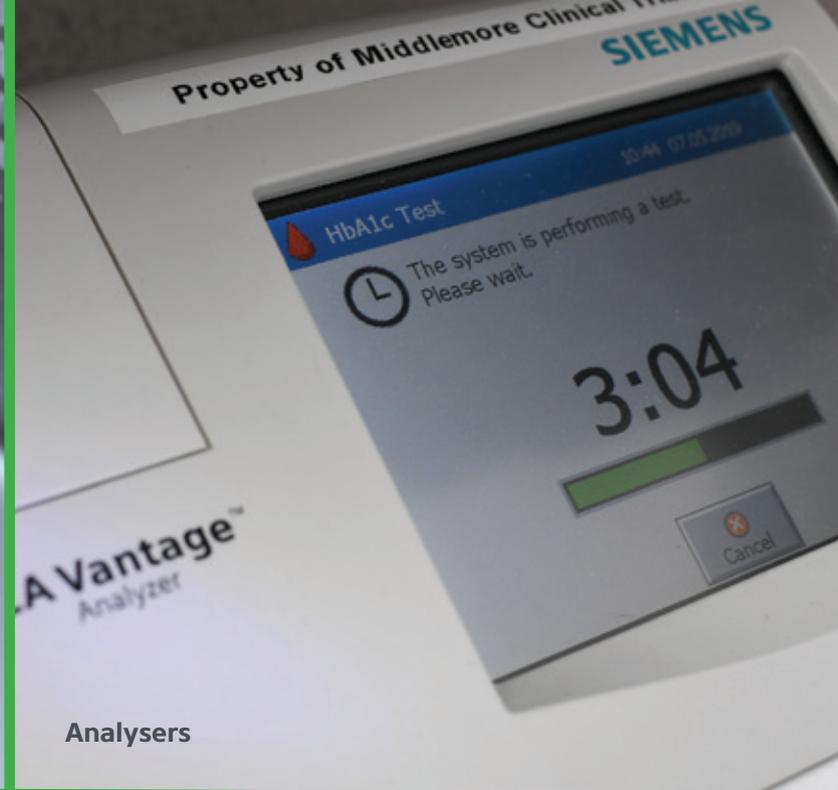
MMCT has 20 years of trial management experience in most therapeutic areas. Our processes are fully and clearly documented in our Standard Operating Procedures.

High quality data

MMCT takes pride in timely completion of Case Report Forms and query resolution. Our study coordinators are dedicated research staff with years of experience in trial management and EDC systems.



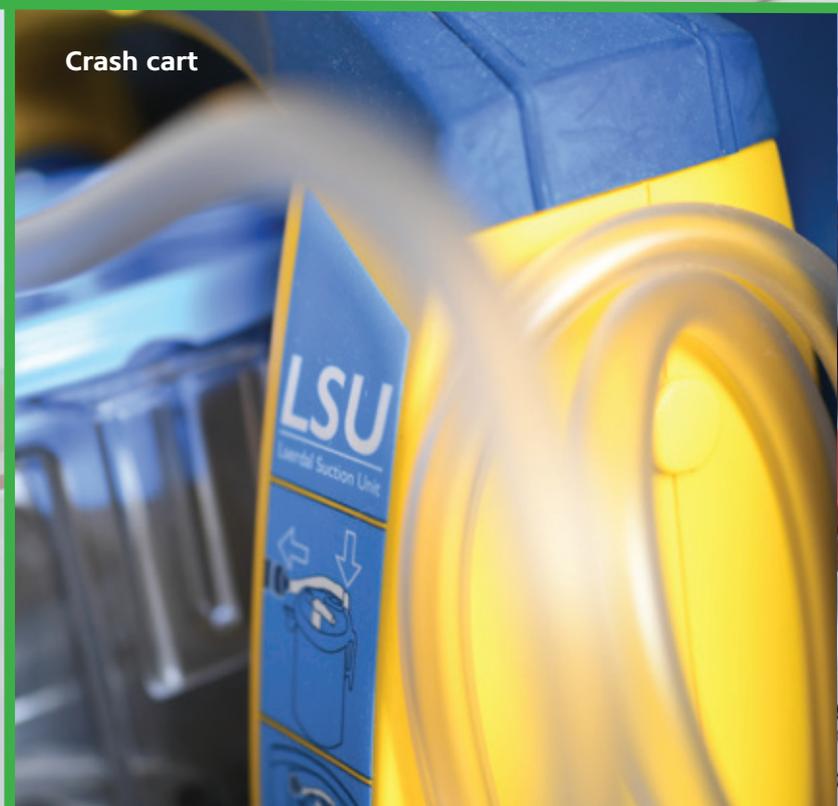
Centrifuges



Analysers



Laboratory



Crash cart



Spirometry



ECG



Pharmacy



Phlebotomy

Site Facilities

MMCT has a full suite of modern facilities

These include a fully equipped on-site pharmacy, a laboratory, and a dedicated trial infusion suite. We maintain eight clinic rooms and a dedicated reception area, all located within a close proximity. MMCT is also situated on the campus of Middlemore Hospital, meaning MMCT has access to the facilities of a large tertiary hospital.

**MMCT is one of New Zealand's best equipped
Clinical Trial facilities**

MMCT's accredited facilities are suitable to conduct most clinical trial protocols. We have our own research facilities, fully equipped with modern equipment.



On-site Equipment

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

On-site Laboratory

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





Pharmacy

MMCT has a secure on-site pharmacy. The pharmacy contains multiple locked IP, temperature controlled cabinets, and five monitored fridges.

MMCT employs a pharmacist to strictly control the pharmacy operations.

Pharmacy

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



Infusion Suite

MMCT has an in-house infusion suite which is 100% dedicated to clinical trials.

The unit is designed to accommodate all infusion studies including chemotherapeutic studies. It contains state of the art infusion chairs, and biometric data monitoring.

The unit sits within our facility & features access controlled entry doors ensuring patient safety and privacy. A nursing station is manned continuously during infusions. The unit itself is temperature controlled and it also has its own IP fridge for short term storage of IP.

Infusion Suite

- **2 Reclining Infusion Chairs**
- **1 Recovery/rest chair**
- **Nurses Station**
- **IP Fridge**

The specialist 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







Thank you for wanting to find out more about our maternal

RSV Clinical Trial

Researchers are looking to learn more about a vaccine for RSV, to see if it may help boost the level of RSV antibodies in pregnant women and their babies. We are currently looking for healthy participants to assist in the R2 arm of this global trial.

[Yes I'm interested](#)

Why are we doing this trial?

Respiratory syncytial virus (RSV) is one of the most common reasons babies are admitted to hospital.

What we learn in this study could possibly help develop an RSV maternal vaccine in the future. Therefore any participation is potentially advancing health outcomes for future babies anywhere in the world.

We are currently recruiting new Clinical Trial participants. So what are we looking for?



Trial Recruitment

At MMCT we pride ourselves of attaining the randomization targets that we set in conjunction with the sponsor and the investigators.

Not all trials recruit the same way. Thus to consistently achieve our high recruitment rate we utilize a myriad of recruitment tools including:

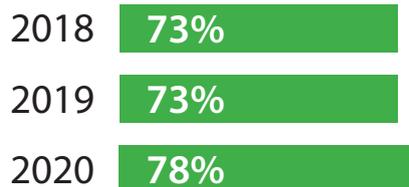
- Experienced specialist recruitment staff
- Comprehensive social media strategies including Google and Facebook ads
- Combining media strategies with the hospital platforms
- Database analysis both in primary care and the hospital
- In-house participant texting service
- Referral phone apps for all hospital clinicians and surrounding GP's.

- Dedicated trial specific landing pages that result in patient interaction.
- Full interaction with our trial management system resulting in continuous call log lead generation

Our results illustrate our drive to not only attract patients but ensure that the adherence rate is high across all studies.

PROVEN PERFORMANCE

TRIALS THAT MET RECRUITMENT TARGETS



Features

The key features of MMCT:

1. Experience in conducting clinical trials across most therapeutic areas, trial phases and complexities
2. Dedicated research facilities and staff
3. Well equipped for large scale trials
4. A reputation built on excellence
5. Access to a large motivated patient population

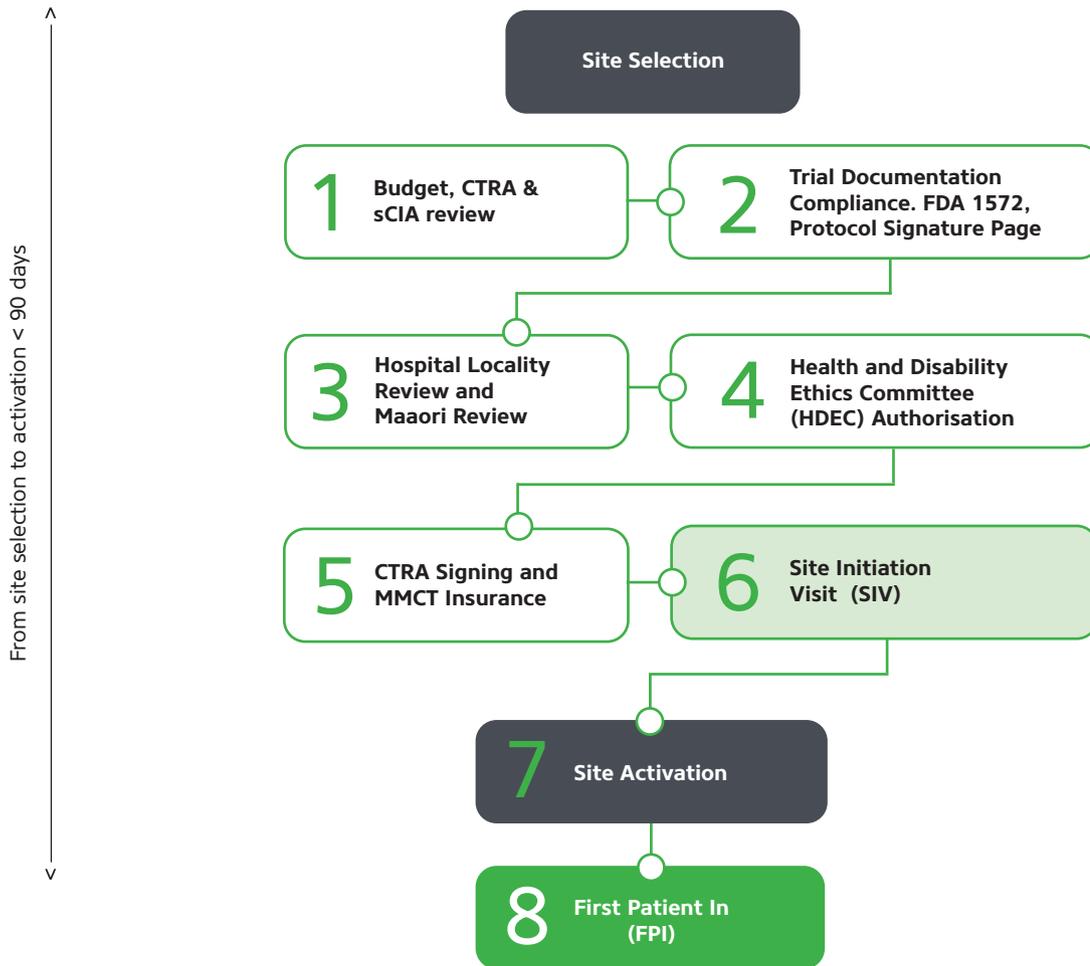
Benefits

The key benefits of our site are:

1. Proven patient recruitment
2. Speed of trial activation
3. Fast access to specialists
4. Quality of data generated
5. Located at a large tertiary hospital

To initiate a partnership with us
contact feasibilities@mmclintrials.nz

Site Activation Process





Samples in preparation for transport



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

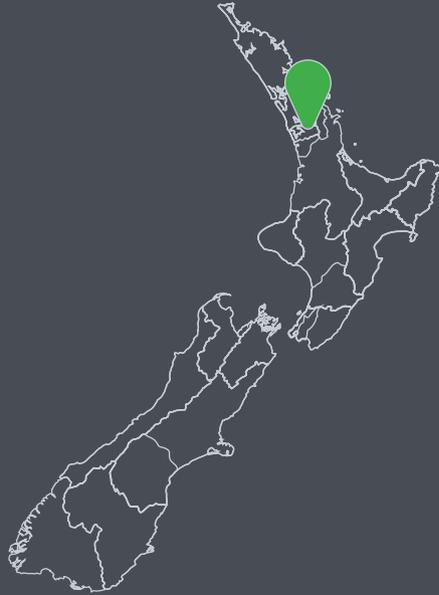
Consented 57. Randomised 30. 100% recruited.
One of the highest numbers recruited in Australasia.

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 literacy for participants, excellent patient compliance.



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