

ANNUAL REPORT 2017

Middlemore
Clinical Trials

Future of healthcare



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About Middlemore Clinical Trials

Clinical trials are research studies that explore whether a medical approach, treatment, or device is safe and effective for humans. These studies may conclude which medical approach or treatment work best for certain illnesses or groups of people.

Middlemore Clinical Trials (MMCT) is a charitable trust that runs clinical trials for pharmaceutical and device companies. As well as this commercial operation, we undertake major grant-funded research studies on behalf of Counties Manukau Health (CM Health). Our role is a balanced mix of commercial and public good functions.

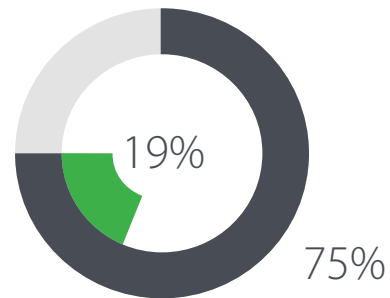
Our business brings high quality and safe pharmaceutical treatments to the people of Counties Manukau through clinical trial research. To do this we provide research facilities and support functions, and employ research nurses. Any surplus funds remaining after trials are completed are held in the Trust's reserves for spending on other research activities.

MMCT has evolved into one of the leading commercial clinical trial sites in Australasia. We pride ourselves on generating high-quality data for our commercial clients. 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 our use of an elite team of research nurse professionals.

Our nurses are dedicated to research and they are multi-skilled across subspecialties. Our flexible work model allows us to change nurse responsibilities and double or triple numbers of nurses working on a particular trial.

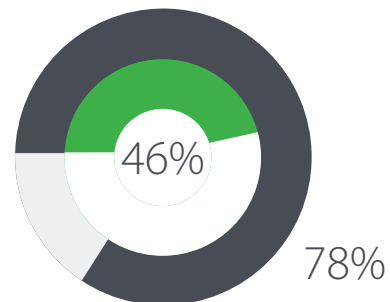
2017 Excellence in trial recruitment

75% Met Recruitment Goal
19% Exceeded Recruitment Goal



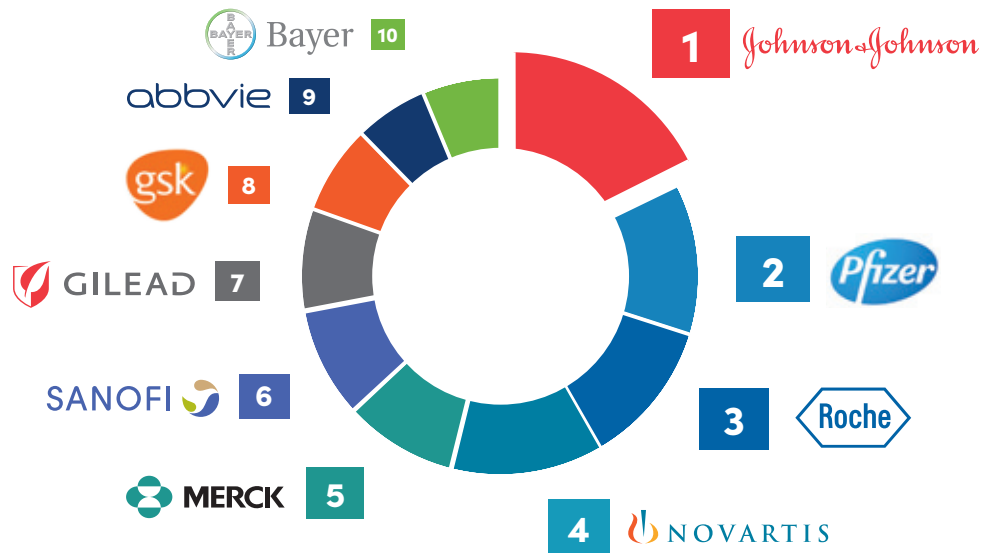
2016 Excellence in trial recruitment

78% Met Recruitment Goal
46% Exceeded Recruitment Goal

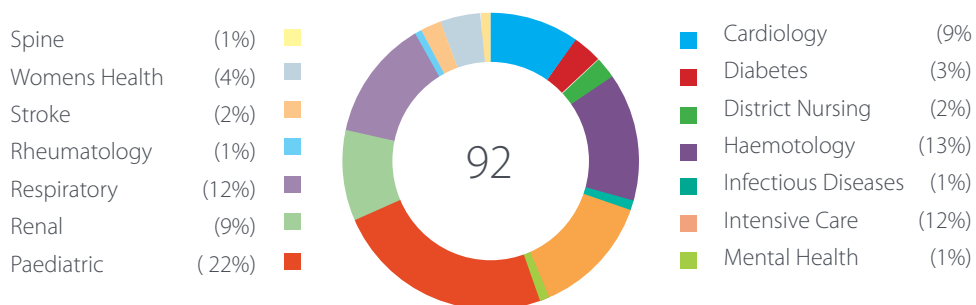


Our business development team is led by a Director of Client Services. The Director of Client Services actively markets MMCT and CM Health as a site for commercial research trials with pharmaceutical industry clients and contract research organisations in NZ, Australia and globally. Seventy percent of new studies which we worked on during FY17 were commissioned by the world's top-ten pharmaceutical companies.

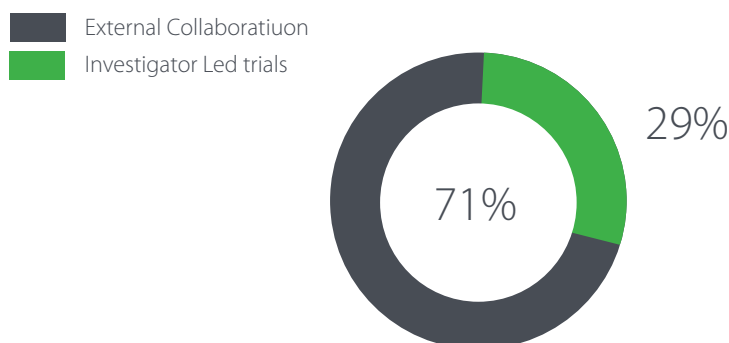
2017 Top 10 Pharmaceutical Companies Globally*



2017 The distribution of the 92 publicly funded clinical trials managed by Middlemore Clinical Trials, by department



2017 Percentage of internal and externally generated publicly funded clinical trials managed by Middlemore Clinical Trials,

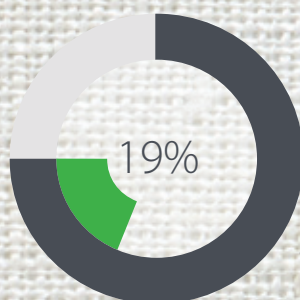


2017 at a glance

66 Active Commercial Trials

564 Participants

**Excellence in
trial recruitment**



75% Met Recruitment Goal
19% Exceeded Recruitment Goal

Benefiting the community

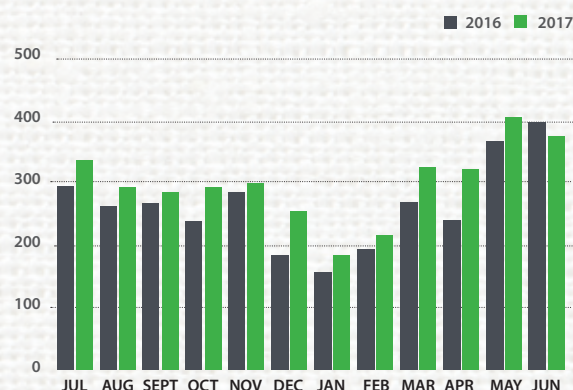
New Patients entering trials in 2017



239 New participants into clinical trials

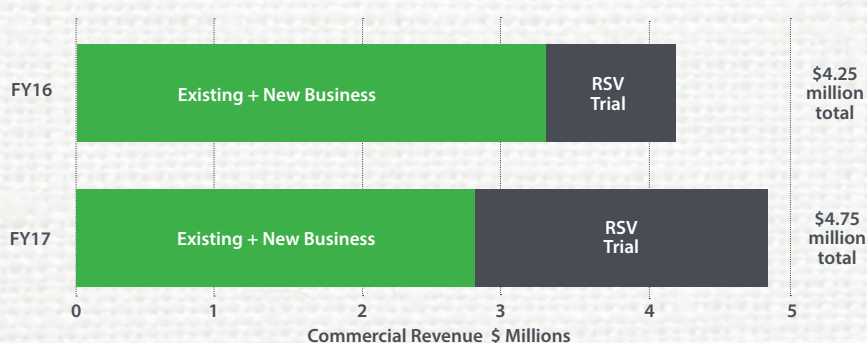
Stable influx of clinical visits

Patients' visits in FY 2017 and 2016



263 Average clinical visits per month

MMCT Commercial Revenue 2016/2017



11.7%

Growth in Commercial Revenue

Patient Story

Tom Russell

Tom Russell was part of a clinical trial that involved over 20,000 participants around the world.

"I was approached immediately after I'd had heart surgery and I must admit that initially I was a bit tentative, but I wanted to repay the medical profession for all their hard work. I also felt that it would be an advantage to not to have to use Warfarin. The staff were very good, kept me fully informed, and discussed each sample. There were no side effects with the new drug and the results have been very encouraging."



Chair's Report

Health research has an increasingly important role for Counties Manukau, by providing critical information about disease trends, risk factors and effective interventions. This is especially true for our people as the area's population grows and diversifies. It is an area with a large number of patients with a range of long-term conditions.

Different research approaches are often complementary, providing a diversity of expertise about medical interventions. Clinical trials are a very important part of the research mix because they link New Zealand patients with the latest developments in treating disease.

We are a unique organisation because we operate as a business, undertaking trials for pharmaceutical companies. But at our heart we are a charity. We reinvest our profits into health research, and undertake studies supported by government and philanthropic funding. We also support and develop research within CM Health.

This year, we wanted to increase the impact we have with our charitable activities. As a result, we have been exploring new ways to use our resources for the greatest benefit. We are excited by a number of new directions we could take. You will read more about some new initiatives in the body of this report.

Financially, we continue to be in a strong position. This reflects the hard work of our entire team in identifying commercial trials that benefit our patient population, and delivering them to the highest standards.

This has also been a challenging year with a number of large event-driven clinical trials finishing before scheduled end-date. However, we are pleased to report continuing strong demand for our services, and increasing revenue.

We were sad to farewell Mariota Smutz in November 2016. Mariota has served on the trust board since 2013. Mariota was replaced as an independent trustee by Marama Parore in May 2017.

2017 saw us welcome KPMG as our new auditor.

Looking ahead I look forward to continuing to increase the profile of health research in Counties Manukau.

We thank you all for your continued support.

Yours sincerely,



Dr Michelle Sullivan

Chair, Middlemore Clinical Trials



Trustees & Executive Team

Michelle Sullivan Chair

Michelle has over 20 years of experience in the life science sector, including biotechnology investment attraction, research and development investment and not-for-profit management. Michelle has a doctorate in protein biochemistry and has experience as a lecturer and a lab-based scientist.

Louise Zacest Deputy Chair

Louise has more than 25 years' experience in product, business and new venture development in the health and financial services sectors in New Zealand and Australia. She is currently Head of Business Development at CM Health and has held previous governance roles with non-profit and financial services businesses.

Dr Gloria Johnson Trustee

Gloria is a trained psychiatrist and has worked in rural and urban settings in Australia and New Zealand. She was Clinical Director of Northland District Health Board's Mental Health Services for four years before becoming its Chief Medical Advisor in December 2007. She has been the Chief Medical Officer at CM Health, since 2012.

Greg Batkin Trustee

Greg holds a BA in Economics and an MBA from the University of Auckland and is the former Chief Investment Officer for Hellaby Holdings, an NZX-listed company with a market capitalisation of circa NZ\$300m. Greg has had more than 20 years investment banking experience at Westpac, ABN AMRO and Craigs Investment Partners. He is currently Chairman of the Board of Directors of Bromley Park Hatcheries, and a director of Safer Sleep, a medical IT business that operates in New Zealand and the United Kingdom.

Marama Parore Trustee

Marama has a background in community nursing, teaching, training and management. She has over 25 years of experience in health including roles with the Public Health Commission, Plunket, the Central Regional Health Authority, Health Funding Authority and as a General Manager for PHARMAC and Pou Ahorangi Chief Executive of Te Rau Matatini (the National Maori Workforce Development organisation). Marama is also the Managing Director of MiHI Ltd – an innovative consultancy working with communities to attain their aspirations.

Dr Doug Wilson Trustee

Dr Douglas Wilson, MB, ChB PhD was originally a medical academic. Since then, he has spent many years in the pharmaceutical industry, firstly as Senior Vice-President for Boehringer Ingelheim USA. Dr Wilson was responsible for all drugs and clinical development and all interactions with the FDA. He then carried these responsibilities worldwide at Boehringer Ingelheim Head Office in Germany. He has overseen multiple drugs at all phases of development including bringing many drugs successfully to the market in the USA. Dr Wilson is now a consultant to the biotechnology sector, and a writer.

The Executive Team

Dr John Baker Clinical & Executive Director

John is an endocrinologist and led the formation of the Diabetes Service at Middlemore Hospital as Clinical Head from 1998-2003. He co-founded Protomix Corporation Ltd in 1999, a biotechnology company investigating novel compounds for the treatment of diabetes mellitus. He went on to become Chief Medical Officer for Protomix for two years before returning to CM Health in October 2005 to take up a dual role as a physician in Internal Medicine for CM Health and as Clinical Director for Middlemore Clinical Trials.

Nicole Signal Director of Client Services

Nicole has over 20 years experience working in drug development, CEO, operations and development roles within a number of venture capital backed start-up biotechnology and drug development companies in New Zealand, Australia, the United Kingdom and the USA. Nicole has a BSc (Hons) in Biochemistry from Monash University and an MBA from Melbourne Business School.

Sandy McGreevy Charge Nurse Manager – Research

Sandy provides leadership to our team of research nurses. In addition to her extensive nursing career in a number of hospitals both here and in the UK, Sandy also lectured in Clinical Nursing at the University of Auckland for a period. Sandy has a Masters of Nursing and is studying towards a Graduate Diploma in Bioethics and Health Law at Otago University.

Clinical & Executive Directors Report

Research in priority areas identified by CM Health in its annual strategic plan is a long-term strategic objective of the trust.

Just over 530,000 residents live in the CM Health district.

The area is multiethnic with high numbers of Māori, Pasifika, Asian and Pākehā. Māori and Pasifika are particularly youthful populations. While the population is ageing, the district has a higher proportion of children than other parts of the country. 36% of the population lives in the most socio-economically deprived areas.

The area's health needs are complex and clinical trials provide an opportunity to explore new treatments and opportunities for CM Health.

FY17 was another successful year for Middlemore Clinical Trials. Our total revenue of \$6.46 million and trading surplus of \$944,726 (+14.6% of revenue) were consistent with budget expectations.

Success was driven by a good all-round recruitment effort over our entire commercial clinical trial portfolio. A number of large trials finished early, which was a challenge. However, these were replaced by new high-quality trials.

Revenue from grant-funded trials declined from FY16 as expected and revenue from interest earnings on investments was steady. Funds held as general reserves increased slightly to \$2.00 million and funds held as designated/restricted reserves increased to \$5.87 million (total reserves \$7.87 million).

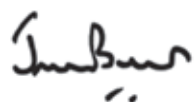
One of the reasons for our success is our flexible work model that allows our Charge Nurse Manager to change nurse responsibilities and double or triple numbers of nurses working on a particular trial – during the critical study enrolment period. Twelve out of 16 recruiting trials in FY17 met target and three trials over-recruited.

Nurse productivity has increased from +122% of target in FY16 to +138% of target in FY17. This is an outstanding achievement. There is a fine spirit of cooperation in the team and this is reflected in a high engagement index in a recent staff satisfaction survey.

As the profitability of the business increases, the trust is turning its attention to increased granting activity from its reserves. This will see more local health research commissioned.

Addressing the burden of metabolic health disorders in Counties Manukau has been a focus for the Trust. In addition to research focused on metabolic health, 8.3% of funds held in designated reserves were spent on research fellows and research nurses, investigator-initiated research projects, research equipment and academic activities.

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



* Trading Surplus is Net Surplus as per Statement of Comprehensive Revenue and Expense (\$289,549), adding back grants (\$351,981) and staff incentives (\$215,875).

About Counties Manukau

- Our older population will increase by approximately 22% by 2020.
- The majority of residents are aged 15-44 years; a statistic not expected to change in the next 10 years.
- We also have more children than any other District Health Board area.
- An estimated 54,000 out of just over 121,000 children are living in poverty.
- Just over a third of residents live in areas of high socioeconomic deprivation.

Projected Population Growth

	0-14 yrs	15-44 yrs	45-64 yrs	65yrs +	TOTAL
2015 (actual)	121,840	218,870	123,390	57,720	521,820
2020	128,030	237,570	134,760	71,390	571,750
2025	130,950	253,040	138,030	86,670	608,690
% Change	7.5%	15.6%	11.9%	50.2%	16.6%

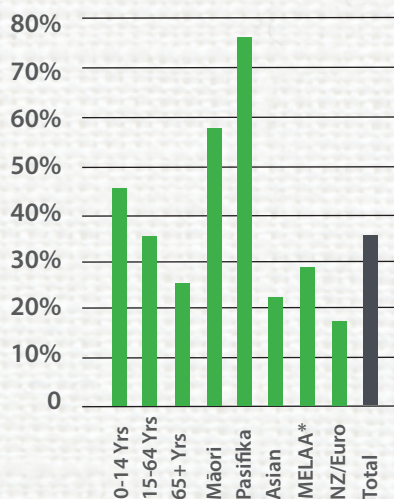
Diversity

- The ethnic mix of the CM population varies by age.
- Younger groups have higher proportions of Māori, Pasifika and Asian.
- Twenty-three percent of the population is aged 14 or under.

Population Composition

	Population (prioritised 2016)	% of CM population	% of NZ that CM pop. represents per ethnicity	% of NZ population
Māori	85,070	16%	12%	16%
Pasifika	112,990	21%	37%	6%
Asian	130,860	24%	21%	14%
NZ Euro/other	205,830	38%	7%	64%
Total	534,750			11%

Proportion of the CM Health population living in socioeconomic deprivation



*Middle Eastern, Latin American or African

Socio-economic status

- Māori and Pasifika residents and children of Counties Manukau are concentrated in the two lowest decile areas (9&10). 58% Māori, 76% of Pasifika peoples, and 45% of the 0-14 years old.

Source: <http://www.countiesmanukau.health.nz/about-us/our-region/population-profile/>

The year in review

FY17 was a challenging year for the team with eight large event-driven clinical trials unexpectedly closing out before their scheduled end-date. But, a continuing and strong demand for our services means that we have been able to replace these trials with new trials.

The Director of Client Services provides a single point of contact and directs clients to relevant clinicians. Over the past year, she has been instrumental in introducing five new investigators to commercial research projects.

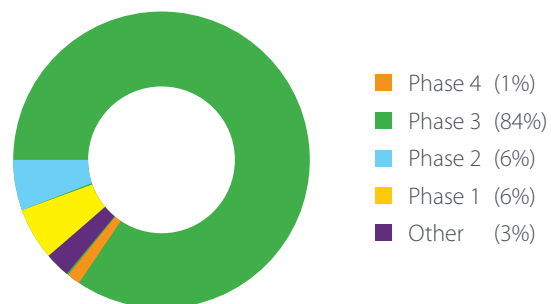
Our investigators are CM Health senior medical consultants. This year we have had 47 investigators engaged in commercial research activities representing 16 departments within Middlemore Hospital.

Trials by department

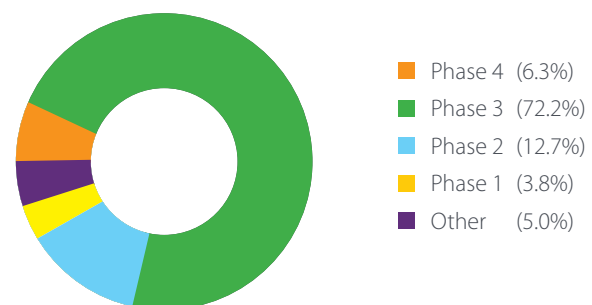
Department	Number of active trials	Number of Participants
Diabetes	17	232
Paediatrics	3	130
Cardiology	7	100
Haematology	19	40
Rheumatology	8	22
Interventional Radiology	5	19
Respiratory	4	13
Hepatology	1	8
Renal	2	0
TOTAL	66	564

We administered a total of 92 commercial trials and 78 grant-funded studies at Middlemore Hospital and Manukau SuperClinic. Our studies are predominantly drug trials of experimental new medicines reflecting the interests of our investigators. We also do a small number of trials of medical devices.

2017 commercial trials by type



2016 commercial trials by type



Most of the drug trials conducted here are studies where drug safety issues have largely been resolved and sponsors and clients are collecting data to support a successful approval by the (USA) Food and Drug Administration (FDA). Many of these studies are event-driven trials lasting many years. This means participants with long-term conditions can receive high-quality, carefully managed healthcare funded by sponsors for many years. This results in a considerable saving to the New Zealand public health system.

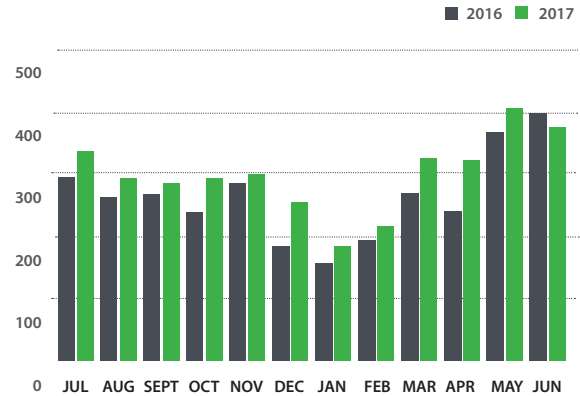
Benefit to CM Health

An estimated 3,163 outpatient clinic visits were saved in FY17 with patients attending clinical trial visits rather than CM Health outpatient clinic appointments.

At an estimated cost of \$212 per clinic appointment, this equates to a potential cost saving of up to \$670,556 per annum.

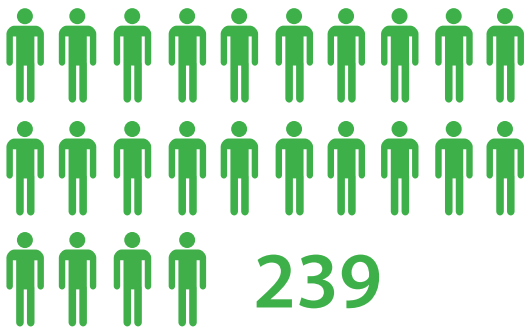
Stable influx of clinical visits

Patients visits in FY 2017 and 2016



Benefiting the community

New participants entering trials in 2017

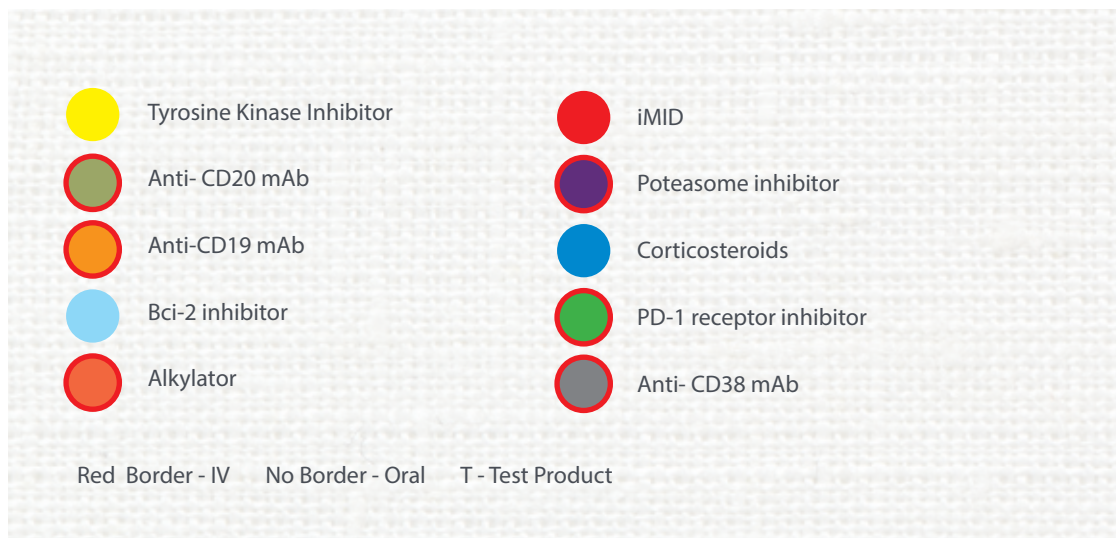
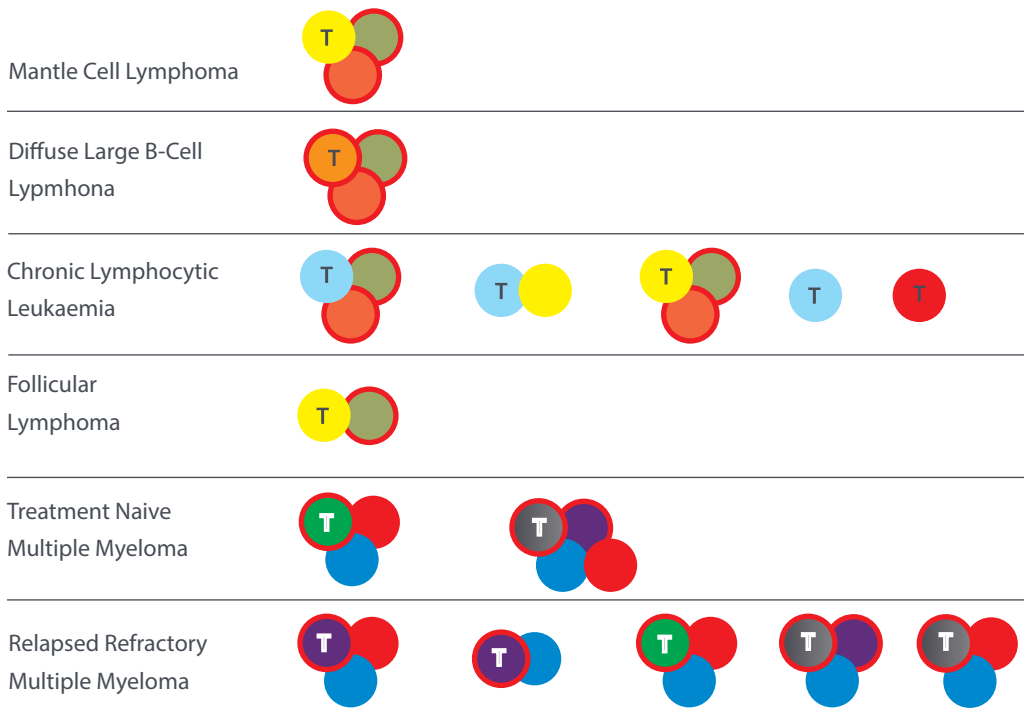


There are also significant savings to participants and CM Health in the cost of drugs provided in clinical trials. In the case of malignant haematology (blood cancers), for example, clinical trial participants receive enhanced anti-cancer therapy. These international medications may not be funded and available in New Zealand.

Currently, MMCT administers 18 malignant haematology trials at Middlemore with 88 participants.

Drug class combinations being trialled

per haematology condition



Patient Story

Fred Herbert

Fred Herbert was having problems with breathing and swelling.

"I'm using quite a few tablets now. I've been part of the trials for almost six or seven years. My life has changed a lot. I can get around more now, it helps me control my weight. Another thing I can say is I've had no pain whatsoever. It's been good because everything gets checked regularly and you're being constantly monitored. All the doctors and nurses are amazing."



Granting

The MMCT Trustees want to tune their focus on the wellbeing of the communities of CM Health, and address health needs for the area. The board's intention is to grow the MMCT business here and in the Pacific, so that it has more resources to invest in local strategies and initiatives. MMCT wants to make best use of its resources for the greater good and explore the opportunities to partner with other allied organisations. A number of projects funded by MMCT were implemented this year.

Diabetes in Pregnancy Registry (DIPR)

This registry project is led by Dr Carl Eagleton (Clinical Director of Medicine & Women's Health physician). The DIPR is based on the highly successful Predict™ and Acute Predict™ registries developed by ENIGMA Software. Predict and Acute Predict assess cardiovascular risk and enables research on patients with coronary heart disease. The DIPR project was funded by a \$105,000 donation from the Middlemore Foundation and the Freemasons Foundation.

The purpose of the DIPR is to allow more effective diabetes screening in women with gestational diabetes after pregnancy; and facilitate early diagnosis and treatment of new-onset type 2 diabetes. MMCT donated project management and contributed a further \$6,450 for compliance testing. By the end of June 2017, 47 women had agreed to participate in the program and eight mothers had given birth.

Based on the early success of this project, Dr Eagleton has reached out to the clinical heads of diabetes in the pregnancy clinics at Auckland City Hospital and North Shore Hospital with a view to extending the project to the entire Auckland Metro area.

INFORMAS Nutrition Survey

The International Network for Food and Obesity/non-communicable Disease Research, Monitoring and Action Support is led locally by Professor Boyd Swinburn, University of Auckland. MMCT donated \$20,755 to fund a research assistant to work on the Foodbank project.

Adolescent bariatric surgery pilot

CM Health has a high prevalence of young people with obesity and youth-onset type 2 diabetes. CM Health offers a bariatric (obesity) surgery program for high-risk adult patients and performs 150 operations per year. These operations have never been performed on adolescents because of risk concerns however. The service is led by Dr Richard Babor (Upper Gastrointestinal surgeon).

Bariatric surgery is widely performed on high-risk obese adolescent patients in centres of excellence in the USA. Dr Babor and Dr Brandon Orr-Walker (Endocrinologist & Head of CM Health Diabetes Service) visited leading adolescent surgery centres in the USA in September 2017 to find out more about methods of candidate selection, pre-operative preparation, and post-operative management. The plan now is to conduct a small pilot surgery project in high-risk obese adolescent patients in FY18.



Adolescent bariatric surgery pilot will target at risk adolescents

Patient Story

Josephine Tangatapoto

Josephine suffers from rheumatoid arthritis.

Two years ago Josephine Tangatopoto had arthritis so badly she could hardly walk. Now she says she is 90% recovered.

"I thought I've got to try this and see how it goes. In the end I loved being part of the trial, the fact that I had the nurse contacting me, reviewing everything. I really listened to the specialist. The tablets have worked and now I don't want to come off them!"



Investment outcomes

Trust reserves

Trust reserves are held as either general reserves or designated/restricted reserves. The Trust charges an administration fee of 20% of gross revenue for all commercial clinical trials. This fee is used to fund infrastructure and any residual funds are added to general reserves. Surplus funds remaining after commercial clinical trials are completed and costs are deducted are allocated to the applicable CM Health departmental fund.

Designated/restricted reserves

Designated and restricted reserves are used to fund a range of research activities that meet MMCT's Trust Deed. Typically, department heads within CM Health will identify research opportunities and these grant requests are considered and approved by the Trust. Total designated/restricted reserves were \$5.86 million at the end of FY17.

Granting Category	Allocation
Research Fellows	\$168,168
Research Nurses	\$106,872
Research costs	\$9,218
Travel awards	\$45,432
Equipment	\$81,331
Publications	\$8,108
IT costs	\$69,695
TOTAL	\$488,826

Trustees have a goal of granting at least 10% of reserve funds per annum. Granting expenditure in FY17 was 8.3% of combined designated/restricted reserves. Nearly two-thirds of the 21 designated or restricted reserves saw granting activity in excess of the trustees' goal. Trustees are beginning to work with CM Health departments to encourage a strategic approach to research activity in their departments and this will be used to guide trust granting activity in the future.

General reserves

General reserves were \$2.0 million at the end of FY17. Good corporate governance and conservatism indicate that circa \$1.5 million should be maintained. This means that \$0.5 million could be spent on new research and advance health outcomes in the coming financial year. In FY17, just over \$100,000 was granted to four worthy projects.

Granting Category	Allocation
INFORMAS Nutrition Survey	\$20,755
Nurse/Allied Health Travel Awards	\$18,736
Metabolic Health Institute: PwC report	\$6,541
DIPR project	\$55,183
TOTAL	\$101,212

Metabolic Health Research

In November 2015, the trustees asked PriceWaterhouseCoopers (PWC) to evaluate the feasibility of establishing a Metabolic Health Institute (MHI) in collaboration with CM Health. The primary focus was to be obesity and metabolic health. We wanted to work in partnership with the community to transform the wellbeing of children and their families.

The recommendations from PWC included a proof of concept phase, whereby MMCT could fund some 'quick win' projects to further explore the feasibility of establishing an MHI. These projects are detailed on page 16.

Travel awards

Two funding rounds for CM Health nurse and allied health staff travel awards were held in August 2016 and February 2017 to attend international conferences.

- The Senior Health Psychologist for Cancer Support received \$4,250 to attend the 18th International Psycho-Oncology Society (IPOS) World Congress in Dublin, October 2016;
- The Clinical Nurse Specialist in Renal Transplant received \$3,660 to attend the 45th European Dialysis and Transplant Nursing Association/European Renal Care Association (EDTNA/ERCA) International Conference in Valencia, Spain, September 2016;
- A Hand Therapist received \$2,650 to attend the World Confederation for Physical Congress 2017 in Cape Town, South Africa, July 2017;
- A social worker with community health service Orakau received \$1,600 to attend the Child & Adolescent Health (Cook Islands Health Conference 2017) in Raratonga, 2017;
- A diabetes nurse specialist received \$4,250 to attend the International Diabetes Federation 2017 Congress in Abu Dhabi, December 2017.

(Case-study)

MMCT Clinical Nurse Educator Diane Caveney explains that drugs – and medical devices and procedures – must go through phases of clinical trials before they can be registered as a new product or procedure. It can take a number of years to achieve registration of a new product. Clinical trials are a critical element in the process of marketing of a new drug, device or equipment.

“A pharmaceutical company will approach us with a new drug or device asking if we would be interested in participating in a clinical trial,” Diane explains.

“Before we accept the pharmaceutical company trial, Middlemore Clinical Trials ensures that we have the participant population group that fits the clinical trial protocol; and a doctor that is keen to lead the trial. Our role is to recruit people with the disease condition that meet the protocol criterion and who are willing to assist with this clinical research.”

Before any clinical trial can proceed in New Zealand it must be granted ethical approval from the NZ Health and Disability Ethics Committee (HDEC). The Ethics Committee scrutinises the trial protocol to ensure the following:

- the safety of the participant is paramount
- their health information is protected
- the established ethical standards, International Council on Harmonisation – Good Clinical Practice (ICH-GCP), and the NZ Code of Rights, are being adhered to

Part of the submission to HDEC includes the participant information and consent form (PICF), which must be written in plain English so the participant understands all aspects of the clinical trial. The PICF contains information around the purpose of the trial, what is required from the participant, the known potential risks and any perceived benefits.

“If the risks were very high without due reason, a trial would not get ethical approval. The number of participants involved in a trial at Middlemore Clinical Trials can vary from a very small sample of three or four up to 200. Typically, however, we are working with 10-30 participants.”

A recent trial tested an implanted device to help lower blood pressure. The outcome of the trial was that it worked well in some participants, but not all. Alistair Drysdale was one of the participants.

“My problem was that my adrenalin was too high and in the end that clouded the results,” says Alistair.

“Even-though the device didn’t work for me, the support and kindness I received were amazing. The heart specialists gave me time I would not normally have had. That was an unexpected benefit. There are some extremely good people there (at CM Health). We can’t afford to lose them. I wish all patients knew how lucky they are.”

The devices were finally removed in October 2017.

Middlemore
Clinical Trials
Future of healthcare



Patient Story

Adhila Kara

Two years ago Adhila was diagnosed with rheumatoid arthritis.

In 2015 it affected her so badly that she couldn't get out of bed. Adhila had to get locums to cover for her at work. After 22 weeks on a clinical trial, she now describes herself as fully functional.

"The treatment was excellent, the communication excellent, I was told what to expect. I was given all the material to read before I started the trial. I am my old self again."





Financial Statements 2017

For Middlemore Clinical Trials Trust

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Approval By Trustees

The Trustees have approved the Financial Statements of Middlemore Clinical Trials Trust for the year ended June 30, 2017 on pages 23 to 34.

For and on behalf of the Trustees.

Trustee

Date

3/11/17

Trustee

Date

3/11/2017

Independent Auditor's Report - Middlemore Clinical Trials Trust



To the beneficiaries of Middlemore Clinical Trials Trust

Report on the financial statements

Opinion

In our opinion, the accompanying financial statements of Middlemore Clinical Trials Trust (the trust) on pages 23 to 34:

- i. present fairly in all material respects the trust's financial position as at 30 June 2017 and its financial performance and cash flows for the year ended on that date; and
- ii. comply with Public Benefit Entity Standards Reduced Disclosure Regime (Not For Profit).

We have audited the accompanying financial statements which comprise:

- the statement of financial position as at 30 June 2017;
- the statements of comprehensive income, changes in equity and cash flows for the year then ended; and
- notes, including a summary of significant accounting policies and other explanatory information.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (New Zealand) ('ISAs (NZ)'). We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

We are independent of the trust in accordance with Professional and Ethical Standard 1 (Revised) Code of Ethics for Assurance Practitioners issued by the New Zealand Auditing and Assurance Standards Board and the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code), and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code.

Our responsibilities under ISAs (NZ) are further described in the auditor's responsibilities for the audit of the financial statements section of our report.

Other than in our capacity as auditor we have no relationship with, or interests in, the trust.

Other information

The Trustees, on behalf of the trust, are responsible for the other information included in the entity's Directory. Our opinion on the financial statements does not cover any other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears materially misstated. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Use of this independent auditor's report

This report is made solely to the beneficiaries as a body. Our audit work has been undertaken so that we might state to the beneficiaries those matters we are required to state to them in the independent auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the beneficiaries as a body for our audit work, this report, or any of the opinions we have formed.

Responsibilities of the Trustees for the financial statements

The Trustees, on behalf of the trust, are responsible for:

- the preparation and fair presentation of the financial statements in accordance with generally accepted accounting practice in New Zealand (being Public Benefit Entity Standards Reduced Disclosure Regime (Not For Profit));
- implementing necessary internal control to enable the preparation of a set of financial statements that is fairly presented and free from material misstatement, whether due to fraud or error; and
- assessing the ability to continue as a going concern. This includes disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless they either intend to liquidate or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objective is:

- to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error; and
- to issue an independent auditor's report that includes our opinion.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs NZ will always detect a material misstatement when it exists.

Misstatements can arise from fraud or error. They are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of these financial statements is located at the External Reporting Board (XRB) website at:

<http://www.xrb.govt.nz/standards-for-assurance-practitioners/auditors-responsibilities/audit-report-8/>

This description forms part of our independent auditor's report.

KPMG

Auckland

3 November 2017

Statement of Comprehensive Revenue and Expense

For the Year Ended 30 June 2017

	June 2017	June 2016
	\$	Reclassified* \$
Revenue from exchange transactions		
Commercial trial revenue	4,747,207	4,251,599
Interest	238,237	257,103
Other revenue	116,671	53,312
Revenue from non-exchange transactions		
Grant funding	1,235,211	2,003,782
Donations	129,472	149,201
Total Revenue	6,466,798	6,714,997
Expense		
Wages and Salaries	2,586,175	2,568,204
Outsourced Personnel	1,657,813	2,320,625
Other personnel costs	199,969	226,512
Trial expenses	531,305	523,096
Administration	322,079	271,291
Occupancy costs	134,695	134,754
Depreciation and amortisation	43,886	33,950
Loss on disposal of property, plant & equipment	–	593
Granting expenses	583,510	293,696
Other	46,150	52,727
Total Expense	6,105,582	6,425,448
Net Surplus / (Deficit)	361,216	289,549
Other comprehensive revenue and expense	–	–
Total comprehensive revenue and expense attributable to the Trust	361,216	289,549

* Certain amounts shown here have been reclassified to reflect Granting activity within it's own cost category.

These Financial Statements should be read in conjunction with the accounting policies on pages 27 to 29 and the notes on pages 30 to 34.

Statement of Changes in Net Assets/Equity

For the Year Ended 30 June 2017

	Attributable to the Trust				
	Contributed Capital	General Reserves	Restricted Reserves	Designated Reserves	Total Net Assets/Equity
	\$	\$	\$	\$	\$
Balance at 30 June 2015 carried forward	100	2,005,232	1,672,487	3,540,270	7,218,089
Total comprehensive revenue and expenses	-	(78,800)	95,768	272,581	289,549
Balance at 30 June 2016	100	1,926,432	1,768,255	3,812,851	7,507,638
Balance at 30 June 2016 carried forward	100	1,926,432	1,768,255	3,812,851	7,507,638
Total comprehensive revenue and expenses		78,226	(5,000)	287,990	361,216
Balance at 30 June 2017	100	2,004,658	1,763,255	4,100,841	7,868,854

These Financial Statements should be read in conjunction with the accounting policies on pages 27 to 29 and the notes on pages 30 to 34.

Statement of Financial Position

For the Year Ended 30 June 2017

		June 2017	June 2016
	Note	\$	\$
ASSETS			
Current Assets			
Cash and Cash Equivalents		499,641	916,051
Term Deposits		5,650,000	4,750,000
Trade and Other Receivables	1	2,924,718	3,700,445
Total Current Assets		9,074,359	9,366,496
Non Current Assets			
Property, Plant & Equipment	2	77,340	59,379
Intangible Assets	3	26,632	41,640
Term Deposits		-	-
Investment - Perpetual Bond		500,000	500,000
Total Non Current Assets		603,971	601,019
Total Assets		9,678,330	9,967,515
LIABILITIES			
Current Liabilities			
Trade and Other Payables	4	1,015,730	1,514,478
Revenue in Advance	5	793,747	945,399
Total Current Liabilities		1,809,477	2,459,877
Net Assets		7,868,854	7,507,638
Reserves			
Contributed Capital		100	100
General Reserves		2,004,658	1,926,432
Restricted Reserves		1,763,255	1,768,255
Designated Reserves		4,100,841	3,812,851
Total Reserves		7,868,854	7,507,638

Represented by:

Statement Of Cash Flows

For the Year Ended 30 June 2017

	June 2017	June 2016
	\$	\$
Cash flows from Operating Activities		
Receipts from donations and other income	246,144	202,513
Receipts from grant funding - non exchange	1,594,427	2,107,244
Receipts from commercial trials - exchange	5,220,375	2,796,664
Interest received	232,731	250,648
Payments to suppliers	(3,872,408)	(3,857,370)
Payments to employees	(2,584,136)	(2,536,241)
GST paid	(306,704)	(78,899)
Net cash flows from/(used in) operating activities	530,429	(1,115,441)
Cash flows from investing activities		
Purchase of property, plant & equipment	(37,214)	(8,943)
Purchase of intangible assets	(9,624)	(56,252)
Net cash flows from/(used in) investing activities	(46,838)	(65,195)
Cash flows from financing activities		
Proceeds from settlement of term deposits	6,450,000	3,587,748
Investment in term deposits	(7,350,000)	(2,716,427)
Net cash flows from/(used in) financing activities	(900,000)	871,321
Net increase/(decrease) in cash and cash equivalents	(416,410)	(309,315)
Cash and cash equivalents at beginning of period	916,051	1,225,366
Cash and cash equivalents at end of period	499,641	916,051

These Financial Statements should be read in conjunction with the accounting policies on pages 27 to 29 and the notes on pages 30 to 34.

Statement of Accounting Policies

For the year ended 30 June 2017

1. Reporting Entity

Middlemore Clinical Trials (The Trust) was established in 2001 as a charitable trust whose key objectives are to undertake, conduct and promote clinical research, evidence-based practice and educational initiatives within the South Auckland region.

The Trust is a charitable trust registered under the Charities Act 2005, and is classified as a public benefit entity for the purposes of financial reporting in accordance with the Financial Reporting Act 2013. The financial statements are for the Trust as a separate legal entity.

The financial statements are for the year ended 30 June 2017.

2. Basis of Preparation

The financial statements have been prepared in accordance with Tier 2 PBE Standards and disclosure concessions have been applied ('PBE RDR'). The Trust is eligible to report in accordance with Tier 2 PBE Standards because it does not have public accountability and is not large (as defined in XRB A1).

The Trust's financial statements have been prepared on a going concern basis. The measurement base applied is historical cost.

The financial statements are presented in New Zealand dollars (\$) which is the entity's functional and presentation currency. All financial information presented in New Zealand dollars has been rounded to the nearest dollar.

Use of Judgements and Estimates

The preparation of the financial statements requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, revenue and expenses. Actual results may differ from those estimates but any differences are not expected to be material.

Judgements made in applying accounting policies that have had the most significant effect on the amounts recognised in the financial statements include the assessment of conditions in the contracts for grant funded trials relating to the return of funds. The outcome of this assessment determines the timing of revenue recognition on these non-exchange transactions.

3. Specific Accounting Policies

The specific accounting policies used in the preparation of the financial statements are as follows.

3.1 Revenue

Revenue is recognised to the extent that is probable that the economic benefits will flow to the Trust and the revenue can be reliably measured.

Revenue is measured at the fair value of the consideration received or receivable and is recorded net of GST.

3.2 GST

The Financial Statements have been prepared using GST exclusive figures with the exception of receivables and payables which are stated GST inclusive.

Revenue from exchange transactions

Exchange transactions are transactions in which an entity gives assets or services, or extinguishes liabilities and directly receives approximately equal value from another entity in exchange.

Commercial trials

Revenue receivable from sponsors for commercial trials is recognised in 'Commercial Trial Revenue' in the Statement of Comprehensive Revenue and Expenses as services are provided.

Amounts received from sponsors in advance of the services being provided are carried as liabilities (Revenue in advance). Revenue awaiting the approval of sponsors for invoicing is reported within debtors as 'Accrued Income'.

A Principal Investigator (PI) is associated with each commercial trial, with most PIs being employees of CMDHB. The net surplus or loss on each trial is attributed to the department to which the PI is attached and held within designated or restricted reserves, unless the PI is an employee of the Trust, in which case the net surplus or loss is held within General Reserves.

Interest income

Interest income is recognised on an accruals basis.

Revenue from non-exchange transactions

Non exchange transactions are transactions in which an entity gives value to another entity without directly receiving approximately equal value in exchange. The fair value of the Trust's non-exchange revenue is measured by the cash receivable.

Grant funded trials and projects

Revenue receivable from grant funding agencies for trials and projects is recognised in 'Grant funding' in the Statement of Comprehensive Revenue and Expenses. Amounts received from

Statement of Accounting Policies

For the year ended 30 June 2017

the grantor are recognised as revenue upon receipt, providing the grant contract does not include conditions requiring the Trust to return funds granted if the conditions are breached or the funds are not spent as stipulated.

If there are such conditions within the contract requiring return of surplus funds, Revenue is recognised in the Statement of Financial Position as Revenue in Advance and the liability is reduced as the PI incurs the eligible expenditure.

A PI is associated with each grant funded trial or project, with most PIs being employees of CMDHB. The net surplus or loss on each trial is attributed to the department to which the PI is attached and held within designated or restricted reserves, unless the PI is an employee of the Trust, in which case the net surplus or loss is held within General Reserves.

Donation income

Donations that are not subject to conditions are recognised as income on receipt.

Other non-exchange income

Other non-exchange income includes amounts received by the Trust in relation to other projects undertaken by PIs (Principal Investigators). Other income is recognised when received if it is not subject to conditions. Other income that is subject to conditions is recognised by applying the accounting policy for 'Grant funded trials and projects'.

3.3 Foreign Currency Transactions

Transactions denominated in foreign currencies are translated into the reporting currency using the exchange rate in effect at the transaction date.

Monetary items receivable or payable in a foreign currency, other than those resulting from short-term transactions covered by forward exchange contracts, are translated at balance date at the closing rate. For transactions covered by short-term forward exchange contracts, the rates specified in those contracts are used as the basis for measuring and reporting the transaction.

Exchange differences on foreign currency balances are recognised in the Statement of Comprehensive Revenue and Expense.

3.4 Taxation

The Trust has been granted charitable status under the Income Tax Act by the Inland Revenue Department; hence it is exempt from income tax. The Trust was re-registered as a charitable entity under the Charities Act 2005 on 4 March 2008.

3.5 Financial instruments

The Trust's financial instruments comprise cash and cash equivalents, term deposits, investments, trade and other receivables, and trade and other payables. Financial instruments are initially measured at fair value plus directly attributable transaction costs. Subsequent measurement is dependent on the classification of the financial instrument, as set out below.

The Trust's financial assets are classified as "Loans and Receivables", being financial assets with fixed or determinable payments that are not quoted in an active market. Loans and receivables are subsequently measured at amortised cost using the effective interest method, less any impairment losses.

The Trust's financial liabilities are classified as "Measured at Amortised Cost", and are non-derivative financial liabilities, subsequently measured at amortised cost using the effective interest method.

3.6 Trade and other receivables

Trade and other receivables are recognised initially at fair value and subsequently measured at amortised cost less provision for impairment.

Collectability of trade receivables is reviewed on an ongoing basis and an impairment provision is recognised when there is objective evidence, such as significantly overdue balances, that the Trust will not be able to collect the receivable.

3.7 Trade and other payables

Trade and other payables are non-interest bearing and are normally settled on 30 day terms. Given their short term nature, the carrying values of trade and other payables are considered a reasonable approximation of their fair values.

3.8 Property, Plant & Equipment

Property, plant and equipment are recorded at cost less accumulated depreciation and impairment losses. Provision is made for any permanent impairment in the value of property, plant and equipment.

All items of property, plant and equipment are depreciated on a straight line basis at rates that will write off their cost less estimated residual value over their expected useful lives.

Depreciation rates used:

Clinical Equipment	15.5% - 18.0%
Information Technology	30.0%
Other Equipment	10.0% - 24.0%

The assets useful lives and depreciation methods are reviewed at least annually and adjusted if necessary.

Restricted Reserves

The restricted reserve balance represents the cumulative net surplus attributable to trials, projects or receipt of other income associated with PIs employed by parties other than the Trust and for which there is a contractual arrangement in place that restricts the use of the funds to the benefit of that PI's department.

A portion of the Trust's net surplus for the year is allocated to designated or restricted reserves, as shown in the Statement of Changes in Net Assets/Equity, being the net surplus or loss attributable to trials, projects or receipt of other income associated with PIs employed by parties other than the Trust.

Applications for use of and disbursements to be made from the designated and restricted reserves are submitted by PIs for review and approval by the Trustees who are responsible for ensuring funds are used in accordance with the Trust deed.

3.9 Intangible Assets

Intangible assets are recorded at cost less accumulated amortisation and impairment losses. Provision is made for any permanent impairment in the value of intangible assets.

All intangible items are amortised on a straight line basis at rates that will write off their cost less estimated residual value over their expected useful lives.

Amortisation rates used:

Intangible assets	30.0% - 40.0%
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The assets useful lives and amortisation methods are reviewed at least annually and adjusted if necessary.

3.10 Impairment

Annually the trustees assess the carrying value of each asset. Where the estimated recoverable amount of the asset is less than its carrying amount, the asset is written down. The impairment loss is recognised in the Statement of Comprehensive Revenue and Expense.

3.11 Employee entitlements

Employee entitlements to salaries and wages, annual leave and other benefits are recognised when they accrue to employees. The liability for employee entitlements is carried at the present value of the estimated future cash outflows.

Defined contribution plans are post-employment benefit plans under which the Trust pays fixed contributions into a separate entity and has no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution plans are recognised as an employee benefit expense in the period during which services are rendered by the employee.

3.11 Reserves**General Reserves**

General Reserves are unrestricted funds which are available for use at the discretion of the Trustees in furtherance of the objectives of the Trust and which have not been designated for other purposes.

Designated Reserves

Designated reserves are unrestricted funds which have been reserved by the Trustees for a specific purpose. The balance includes the cumulative net surplus attributable to trials, projects or receipt of other income associated with PIs employed by parties other than the Trust but for which there is no contractual arrangement in place to establish the restriction.

3.12 Leases

Leases under which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases net of any incentives receivable are recognised as an expense in the Statement of Comprehensive Revenue and Expense on a straight line basis over the lease term.

Notes to the Financial Statements

For the Year Ended 30 June 2017

1 Trade and other receivables

	June 2017	June 2016
	\$	\$
Trade receivables - exchange	698,348	1,548,920
Trade receivables - non exchange	163,617	326,722
Accrued Income - exchange	1,818,458	1,359,815
Accrued Income - non exchange	400	45,146
Interest income accrued	102,648	97,142
Other debtors	51,270	268,656
Prepayments	52,519	54,044
GST Receivable	37,457	-
	2,924,718	3,700,445

2 Property, Plant and Equipment

	Clinical Equipment	Information Technology	Other Equipment	Total
	\$	\$	\$	\$
Cost				
Balance as at 1 July 2016	144,591	22,539	21,220	188,350
Additions	29,282	1,870	6,062	37,214
Disposals	-	-	-	-
Balance as at 30 June 2017	173,873	24,409	27,282	225,564
Accumulated Depreciation				
Balance as at 1 July 2016	93,421	22,396	13,154	128,971
Depreciation expense	15,536	453	3,265	19,253
Balance as at 30 June 2017	108,957	22,849	16,419	148,224
Carrying amounts				
As at 30 June 2016	51,170	143	8,066	59,379
As at 30 June 2017	64,917	1,560	10,863	77,340

Notes to the Financial Statements

For the Year Ended 30 June 2017

3 Intangible Assets

	IT Software
	\$
Cost	
Balance as at 1 July 2016	61,642
Additions	9,624
Disposals	-
Balance as at 30 June 2017	71,266
Accumulated Amortisation	
Balance as at 1 July 2016	20,002
Amortisation expense	24,632
Balance as at 30 June 2017	44,634
Carrying amounts	
As at 30 June 2016	41,640
As at 30 June 2017	26,632

Capital work in progress

The balance above includes capital work in progress of \$nil (2016: \$7,413)

4 Trade and Other Payables

	June 2017	June 2016
	\$	\$
Trade Payables - exchange	116,933	106,843
Trade Payables - non exchange	31,274	45,298
Trade Creditors - CMDHB	333,559	395,408
Accruals	178,503	520,443
Employee Entitlements	355,461	353,422
GST Payable	-	93,064
	1,015,730	1,514,478

Notes to the Financial Statements

For the Year Ended 30 June 2017

5 Revenue in Advance

	June 2017	June 2016
	\$	\$
Revenue in Advance - exchange	24,015	41,534
Revenue in Advance - non exchange	769,732	903,865
	793,747	945,399

6 Financial Instruments by Category

2016	Financial Assets Loans & Receivables	Financial Liabilities Amortised Cost
	\$	\$
Cash and cash equivalent	916,051	-
Term Deposit	4,750,000	-
Perpetual Bond	500,000	-
Receivables	3,646,401	-
Payables	-	1,421,414
Balance at 30 June 2016	9,812,452	1,421,414

2017	Financial Assets Loans & Receivables	Financial Liabilities Amortised Cost
	\$	\$
Cash and cash equivalent	499,641	-
Term Deposit	5,650,000	-
Perpetual Bond	500,000	-
Receivables	2,872,200	-
Payables	-	1,015,730
Balance at 30 June 2017	9,521,841	1,015,730

Notes to the Financial Statements

For the Year Ended 30 June 2017

7 Contingent Liabilities

There were no known contingent liabilities as at 30 June 2017 (2016:Nil)

8 Commitments

8 (a) Capital Commitments

The Trust had no capital commitments as at 30 June 2017 (2016: Nil)

	June 2017	June 2016
	\$	\$
8 (b) Operating Lease Commitments		
The future non-cancellable minimum lease payments under operating leases at reporting date are payable as follows:		
Within one Year	67,109	134,219
Later than one year but no longer than five years	-	67,109
Later than five years	-	-
	67,109	201,328

There are two rights for a further three years renewal each, and further terms are negotiable in good faith thereafter. The lease expense for the year of \$134,219 (2016: \$134,219) is included within occupancy costs in the statement of comprehensive revenue and expense.

9 Related Parties

9 (a) Related Party

The Counties Manukau District Health Board (CMDHB) has influence on the Trust through representation on the Trust Board, access provided to medical personnel and the value of transactions that occur between the parties.

CMDHB supplies the premises (see Note 9b), medical personnel that assist with the trials, makes purchases on the Trust's behalf and remunerates the Chair of the Trust (see Note 9b). The total purchased from CMDHB in 2017 was \$2,455,590 (2016:\$2,070,681).

Purchases are expensed or capitalised in the Trust's financial statements as appropriate and the Receivable and Payable balances are disclosed in Note 1 and 4.

Notes to the Financial Statements

For the Year Ended 30 June 2017

9 (b) Key Management Personnel

The Trust classifies its key management personnel into one of two classes; members of the Board of Trustees and Executive Management, responsible for the strategic direction and operational management of the Trust, reporting to the Board of Trustees.

	June 2017	No of Individuals	June 2016	No of Individuals
	\$		\$	
Board trustees remuneration	24,725	6	7,000	5
Executive management remuneration	766,305	4	538,742	4
	791,030		545,742	

Outstanding amounts are included in Note 4 'Employee Entitlements' as at 30 June 2017 \$155,019 (2016: \$190,838).

The Board of Trustees consisted of 6 members as at 30 June 2017. During the current year one member resigned in November 2016 and two members were appointed in November 2016 and May 2017. Three of the members provide their services voluntarily, the chair and the others are remunerated.

The Clinical and Executive Director at the Trust is an employee of CMDHB, with the Trust being charged for the time attributable to Trust activities.

Middlemore Clinical Trials Trust - Directory

As at 30 June 2017

TRUSTEES

Michelle Sullivan (Chair), Louise Zacest, Gloria Johnson, Mariota Smutz (resigned Nov-16), Greg Batkin (appointed Sep-16), Marama Parore (appointed May-17).

Subsequent to 30 June 2017 Doug Wilson has resigned (Aug-17) and Margie Apa has been appointed (Sep-17).

NATURE OF BUSINESS

Middlemore Clinical Trials (the Trust) was established in 2001 and is a Charitable Trust based at Middlemore Hospital. Middlemore Clinical Trials undertakes clinical research trials and projects for commercial sponsors and grant funding agencies, working with Counties Manukau District Health Board's (CMDHB's) clinicians ("Principal Investigators" or "PIs"), Middlemore Clinical Trials own research staff and other resources such as CMDHB's nursing staff. Residual monies left over when research projects are complete are retained in the Trust's reserves, to be used in accordance with the objectives of the Trust, for example the support of further investigator-initiated research and academic activities. The Trust maintains extensive Professional Indemnity and Public Liability insurance and indemnifies CMDHB in the event of a claim.

AUDITORS

KPMG

SOLICITORS

Adina Halpern, Solicitor and Barrister

BANKERS

ASB Bank Limited

REGISTERED OFFICE

Hospital Road

Private Bag 93311

Otahuhu

AUCKLAND

**Middlemore
Clinical Trials**

Future of healthcare

