AUGUST 2024

SCOPE 84

A MALAGHAN INSTITUTE PUBLICATION

MALAGHAN INSTITUTE OF MEDICAL RESEARCH

Phase 2 clinical trial underway to confirm effectiveness and safety of NZ's first CAR T-cell cancer therapy

WHAT'S INSIDE

From the Director

The exciting news of our ENABLE-2 CAR T-cell trial getting underway last month means many more lives can be saved from a potentially terminal blood cancer diagnosis. It's progress like this that gets everyone here at the Malaghan out of bed each morning.

Significantly, it also brings New Zealand one step closer to CAR T-cell therapy becoming a standard of care for cancer – a goal we have been working towards for many, many years.

Delivering treatments like CAR T-cell therapy in our healthcare system requires a fundamental shift in mindset here in New Zealand – a country which has never seen a locally developed therapy taken all the way to market.

Our loved ones can't afford to wait in the back of the line for life-saving treatment. Your support signifies more than just a financial investment; it's a catalyst for revolutionising healthcare delivery. By backing our biomedical research, you're driving innovation, fostering collaboration and positioning New Zealand as a pioneer in cutting-edge medical advancements.

Professor Graham Le Gros | Director
CNZM FRSNZ FRCPA (Hon)

Phase 2 clinical trial underway to confirm effectiveness and safety of NZ's first CAR T-cell cancer therapy

A phase 2 clinical trial of a new CAR T-cell therapy kicked off at Wellington Hospital in July, on the back of promising phase 1 results that suggest improved safety compared with leading commercial CAR T-cell therapies, while remaining highly effective for B-cell non-Hodgkin lymphomas.

Chimeric antigen receptor (CAR) T-cell therapy is a personalised cell therapy, in which a patient's own immune cells are reprogrammed to recognise and eliminate cancer cells. Malaghan Institute Clinical Director Dr Robert Weinkove says commencing a phase 2 trial is a major step towards CAR T-cell therapy becoming a standard of care for certain blood cancers in New Zealand.

"We have final regulatory and ethical approvals, our first site is ready to go, and clinicians around New Zealand have been advised of the criteria and how to refer patients. We hope this new trial will confirm effectiveness and safety of our new NZ-developed CAR T-cell therapy and result in registration for routine use in New Zealand and overseas."

Within the ENABLE-2 trial, 60 adults with certain types of relapsed or refractory large B-cell non-Hodgkin lymphoma will be treated over two years. After assessing the dose and safety of this new CAR T-cell therapy in a phase 1 trial where patients had exhausted all other treatments, patients will be treated earlier in their treatment pathway for ENABLE-2.

"We are hopeful that treating patients earlier – as a second- or third-line therapy – will result in even better CAR T-cell outcomes as their immune system function may have been less damaged by their prior cancer treatments. This may also limit the need for patients to go through repeated chemotherapies with diminishing returns," says Dr Weinkove.

▲ Cover image: The ENABLE 2 team

What's the difference between the phase 1 and phase 2 CAR T clinical trial?

PHASE ONE

Treated 30 patients who had exhausted all other treatment options

Single trial location, in-patient treatment

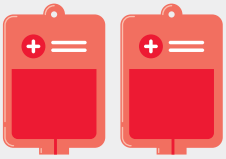
Assessed safety and optimal dose

PHASE TWO

60 patients, will be treated earlier in their disease course

Multi-site trial across NZ, out-patient treatment

Assesses effectiveness and safety, integration with NZ healthcare system



"The safety profile of our new CAR T-cell therapy also means we can deliver it as an outpatient treatment, lowering the burden on patients and their whānau, and reducing costs to the health system."

The Malaghan Institute started New Zealand's first trial of CAR T-cell therapy in late 2019, in collaboration with Wellington Zhaotai Therapies Limited, to assess the safety of a new 'third generation' CAR T-cell therapy and develop and support the regulatory and clinical environment for safe CAR T-cell delivery in New Zealand.

In the ENABLE phase 1 trial, 30 New Zealanders were treated with the new CAR T-cell therapy, with results showing no limiting toxicities and more than half the patients in complete response three months after treatment.

ENABLE also established automated manufacture and delivery of CAR T-cells by BioOra Limited, a New Zealand start-up incubated at the Malaghan Institute and established with Bridgewest Ventures in 2021 to optimise and scale-up CAR T-cell manufacturing in New Zealand.

"Automation offers efficiencies and scalability that will lower barriers to this ground-breaking treatment," says BioOra Managing Director John Robson. "Our unique automated process for this personalised therapy will enable us to manufacture CAR T-cells more consistently at lower cost, and to treat more patients – for this trial and beyond."

Dr Weinkove says the Malaghan Institute and BioOra are in active discussions with government and health sector colleagues about next steps, while putting in place the manufacturing, distribution and health service integration measures that could establish this therapy as a standard of care if the phase 2 trial is successful.

"A number of CAR T-cell therapies have been registered based on phase 2 trials. One of the key objectives of the phase 2 trial is to support registration of our CAR T-cell therapy in New Zealand and Australia. We would like to maximise the chances of timely uptake within the public health system to limit gaps in treatment availability for those who need it," says Dr Weinkove.

> "We are hopeful that treating patients earlier – as a second- or third-line therapy – will result in even better CAR T-cell outcomes as their immune system function may have been less damaged by their prior cancer treatments."

"As a charity, the Malaghan Institute is hugely grateful to and reliant on our funders and donors for helping us bring this ground-breaking therapy to New Zealand, and demonstrate a new way to bring innovative, affordable new treatments into the New Zealand healthcare system."

Research deepening our understanding of elusive eosinophils

Research by the Le Gros Laboratory has deepened our understanding of the diversity of eosinophils, a type of immune cell involved in a range of diseases from parasitic infections to cancer. The study, published in *Immunology & Cell Biology*, helps further understanding of how immune cells protect us from disease.

▲ Sophia Noble

Of the many different kinds of immune cells, eosinophils are one of the more mysterious. Commonly grouped within the wider category of white blood cells, eosinophils are most commonly associated with infections from intruders like parasites.

However, their exact role isn't yet clear. On the one hand, eosinophils play a regulatory role in homeostasis – keeping the gut and other parts of the body on an even keel. Yet, other research has shown that in cases like asthma, they contribute to pro-inflammatory responses, driving the progression of the disease. Understanding these elusive immune cells is an important step towards harnessing them to help fight disease.

> "Our goal is to continue studying eosinophil diversity with the ultimate aim of understanding what makes an eosinophil beneficial or pathological and how we can target specific types of eosinophils in disease."

"We think that, as with all immune cells, the primary role of eosinophils is to protect the body and maintain homeostasis," says Malaghan Institute PhD student Sophia Noble, who led this research as part of her thesis. "However, if eosinophils become overactive this can have unwanted side effects and can contribute to the cycle of inflammation, cause tissue damage and contribute to disease.

"In this research we wanted to understand more about eosinophils, and specifically, how they respond and change during parasite infection and other challenges to the lung. We wanted to comprehensively characterise eosinophil subtypes following infection."

Using flow cytometry, Sophia studied eosinophils in the lungs of mice that were infected with the parasitic worm Nippostrongylus brasiliensis. She found that upon exposure, the eosinophils differentiated into two distinct subtypes, migrating to different locations in the lungs and producing different kinds of chemical markers. This was also the case with other kinds of challenges to the immune system, such as exposure to dust mites, suggesting this diversity is an important part of how eosinophils function when fighting disease.

"These kinds of findings are important as they suggest we can't take a heavy-handed approach to targeting immune cells like eosinophils for therapies. Eosinophils are part of the innate immune system. The innate arm of the immune system is the first line of defence, with innate immune cells responding rapidly to a broad range of invading pathogens," says Sophia.

"For a long time innate immune cells were considered to be a blunt tool of the immune system, with limited adaptability and diversity. However, we now know that innate immune cells, such as eosinophils, are diverse and contribute to a variety of functions. Understanding this diversity and the signals that drive it is essential for understanding human immunology and improving disease treatment.

"Our goal is to continue studying eosinophil diversity with the ultimate aim of understanding what makes an eosinophil beneficial or pathological and how we can target specific types of eosinophils in disease."

International collaboration finds lipid imbalance in the skin may contribute to inflammatory conditions

▲ Dr Olivier Lamiable, Professor Franca Ronchese, Dr Sotaro Ochiai

An imbalance of lipids in the skin may be a contributing factor to psoriasis according to a collaboration between the Malaghan Institute and Seoul National University. The findings offer vital clues in understanding the complex relationship between the skin, the immune cells that call it home, and our health.

"Led by our collaborator Professor Yeonseok Chung from Seoul National University, we investigated the intricate relationship between the skin-residing immune cell populations, their mediators, and lipid metabolism during psoriasis, a chronic inflammatory skin disorder, affecting 125 million people world-wide," says Malaghan Institute research fellow Dr Sou Ochiai.

"Lipids are compounds derived from fats and oils, important for storing energy and forming cell membranes in the body. Our study revealed the disruption in lipid metabolism within psoriatic skin compared to healthy skin. Interestingly, we found this lipid imbalance and disease severity were more pronounced in the absence of the chemical signalling molecule IL-13, a key mediator always produced in healthy skin and strongly upregulated during allergic conditions."

The skin is the first line of defence against the many allergens and harmful microorganisms we encounter on a daily basis. The immune cells that live in the skin are vital for maintaining the integrity and function of the skin, and play a central role if things go awry – as is the case with allergic and inflammatory conditions. Understanding why these conditions happen, and how we can potentially stop them, is key to developing new treatments or preventing it from happening in the first place.

Previous work from the Malaghan Institute showed skin-resident immune cells also play a much larger role throughout the body, likening the skin to a 'ground zero' for the development of these life-long and often debilitating allergic and inflammatory conditions. This recent research, published in *Cell Reports*, expands on this, demonstrating how reduced IL-13 can lead to lipid imbalance and compromise the integrity of the skin as well as its ability to control inflammation.

> "Understanding the skin's immune responses is essential for treating allergic reactions and other inflammatory diseases."

"Lipids play a crucial role in maintaining the function and integrity of the skin barrier," says Dr Ochiai. "Disruptions in lipid homeostasis can compromise the skin barrier, making it more susceptible to infections and increasing the likelihood of conditions such as atopic dermatitis and psoriasis. In addition to their role in physical barrier functions, lipid-derived mediators can also regulate the immune system."

Dr Ochiai says there is strong evidence that the skin is the initial site where allergens come in contact before triggering allergic inflammation, in not only skin but also in the lungs and gut.

"Understanding the skin's immune responses is essential for treating allergic reactions and other inflammatory diseases. This research highlights the broad impact of immune cells and their products on normal skin function, and offers new avenues for developing treatments for skin diseases that could be translated into clinical interventions."

MALAGHAN ALUMNI

Professor John Holloway

Professor John Holloway is a Professor of Allergy and Respiratory Genetics at the University of Southampton in the United Kingdom. He worked at the Malaghan Institute from 1994–97, completing his PhD on the genetics of asthma. John fondly recalls how his time at the institute taught him to be curious and not be afraid to ask why.

▲ Clockwise from left - Franca Ronchese, Graham Le Gros, John Holloway, Rod Dunbar

Where did you grow up?

I spent my early years in Dunedin and, after a year in Scotland, returned to Wellington where I attended Roseneath Primary School and Wellington College.

Where were you before your time at the Malaghan Institute?

I was studying Biochemistry at Otago University followed by a short research placement in the Wellington School of Medicine while I figured out what I wanted to do with my life. I had been awarded a PhD scholarship and decided to do a project studying the genetics of asthma with Professor Richard Beasley. The first 18 months of my PhD were spent at the University of Southampton in the UK with Prof Beasley's collaborators, and when I returned I joined the Malaghan Institute (then located at the Wellington School of Medicine) and acquired another supervisor – one Professor Le Gros.

What are some memorable experiences of your time at the Malaghan?

I have so many enduring memories of the two and a half years I spent at the Malaghan and this time shaped me as a scientist in so many ways. I remember the buzz about the place, the fact you could be presenting a paper in journal club one week and being encouraged to design an experiment to test a crazy idea the next. People felt free to get involved in things that interested them. I spent at least six months working on a project testing the effect of BCG vaccination on allergic airway responses that came about because of one of those discussions at the famous journal clubs, and which had nothing to do with my PhD project, yet for many years was my most highly cited paper.

What's been your career path since the Malaghan?

I returned to the UK after submitting my PhD, as during my time in Southampton, I had got engaged to Judith who was still finishing her PhD. Luckily I had a postdoc opportunity in Southampton to continue my PhD studies. Many years later, I am still at the University of Southampton though now as Professor of Allergy and Respiratory Genetics and also Associate Vice-President (Interdisciplinary Research) for the university.

How has your time at the Malaghan Institute influenced your career?

The most important skill I learnt at the Malaghan was to ask questions and be curious. Don't be afraid to ask why? I still tell my students today that in my group there are no stupid questions, just stupid people who don't ask questions.

Where are you working now and what's the focus of your research or role?

In the Faculty of Medicine in Southampton I lead a research group that is seeking to understand the early life origins of allergic and respiratory disease, exploring the mechanisms of prenatal programming of respiratory disease and epigenetic mechanisms underlying atopy and asthma susceptibility.

In my role as Associate Vice-President Interdisciplinary Research at the university I co-lead a range of initiatives including sandpit events, a pump-priming grant scheme and supporting interdisciplinary research institutes to encourage and support researchers from different disciplines to work together to solve societal challenges. I also have roles across the institution in sustainability, both in how we do research and how we can use our research to address sustainability issues in society.

What's your advice to young New Zealand scientists today?

Be bold, be curious, don't be afraid to ask the big questions. Don't think that you can't have an impact on the world because you come from a small country a long way from anywhere.

Malaghan scientists appointed in leadership roles in New Zealand's RNA Platform

New Zealand's RNA technology platform, a collaborative effort to advance RNA technologies in New Zealand, has appointed Malaghan scientists Dr Rebecca McKenzie and Dr Lisa Connor as pillar leads.

These leadership appointments are a key milestone in laying the groundwork for the new platform. Seven pillar leads have been established to cover the processes involved in researching, testing and implementing RNA technologies to benefit New Zealand.

"Inspired by the success of mRNA Covid-19 vaccines, the platform aims to build RNA technologies that can treat cancer, autoimmune diseases, infections and rare diseases," says Professor Kjesten Wiig, co-director of the RNA Platform and deputy director of the Malaghan Institute.

"Rebecca in her role as pillar lead of quality control and Lisa leading preclinical efficacy will be responsible for developing and driving work programmes that will lift New Zealand's capability in RNA production, characterisation and use."

Dr McKenzie has been leading the molecular biology core within the Hugh Green Cytometry Centre at the Malaghan Institute, working to identify and adopt new technology platforms. She has worked with national and international collaborators across disciplines to establish mRNA vaccine technology as a tool for researchers.

Dr Connor is a cellular immunologist at Te Herenga Waka – Victoria University of Wellington and head of the vaccine evaluation team for Vaccine Alliance Aotearoa New Zealand – Ohu Kaupare Huaketo. She leads a research team which investigates the immunobiology of vaccination, specialising in mucosal vaccines and harnessing mRNA technology to develop smarter antigens.

▲ Dr Lisa Connor and Dr Rebecca McKenzie

The platform is being funded by a $70 million government investment over seven years. So far, the platform has awarded grants to projects around the country, encompassing a diverse range of areas within RNA research, including the development of mRNA vaccines, exploration of disease drivers and the formulation of RNA therapeutics.

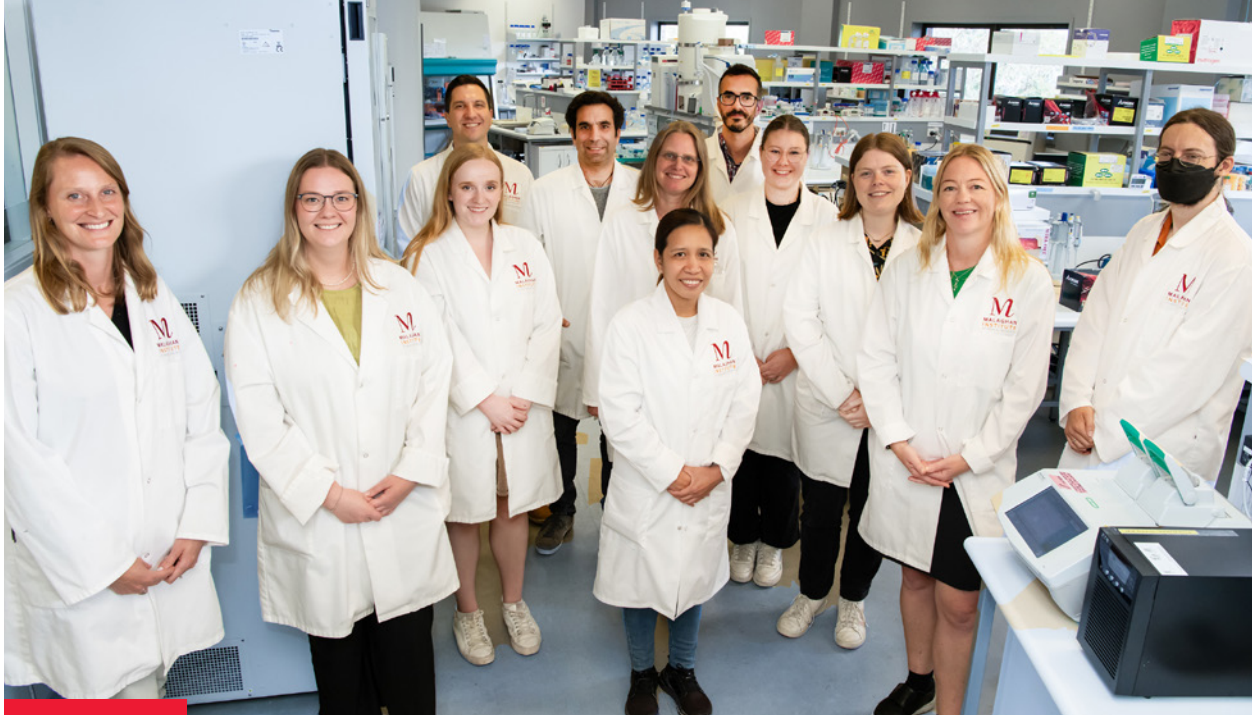
After this initial phase, the platform will select projects that show the greatest promise to take to the clinic to develop into therapies.

> "This platform grants us the freedom to develop innovative solutions for our unique challenges, solutions that could go on to make an impact globally."

"The platform aims to build New Zealand's capability to build RNA-based medicines, encourages international teamwork among scientists, and ensures rapid vaccine development for future pandemics, benefiting both human and animal health," says Professor Wiig.

"It's an exciting time for New Zealand science. This platform grants us the freedom to develop innovative solutions for our unique challenges, solutions that could go on to make an impact globally."

"By any measure their respective contributions are remarkable and without question underpin the Malaghan as an internationally recognised world-class independent medical research institute."



▲ The Hugh Green Technology Centre team

Hugh Green Technology Centre: driving innovation and support of medical research

Our research technology hub, the Hugh Green Cytometry Centre, has been renamed the Hugh Green Technology Centre, to better reflect the broader capabilities and technologies this world-leading centre provides in supporting cutting-edge research at the Malaghan Institute and across New Zealand.

"Technology lies at the heart of research," says Chief Technology Officer Kylie Price. "Over the past seven years, we have been steadily expanding our horizons and technology platforms to support research at the Malaghan and beyond. We now offer a much wider range of services than just cytometry. The rename is primarily to reflect what we already are; a national technology centre."

The Hugh Green Foundation, a charitable trust dedicated to improving living standards and social well-being in New Zealand communities, has underpinned funding the Malaghan Institute's research technology capabilities for more than 12 years. Initially focused on building capacity and expertise in flow cytometry, a scientific technique used to uncover critical information about cells – the centre quickly expanded to include microscopy, genomics and more recently in data science. The Hugh Green Foundation recently pledged an additional $15 million investment over the next five years to further expand capacity in flow cytometry and bioimaging, establish integrated capabilities in data science and genomics, and build a national bioanalytical services offering.

"We're democratising access to cutting-edge technologies to advance medical research and foster innovation across New Zealand," says Kylie. "We do this by offering a suite of advanced technologies and comprehensive training for researchers to analyse individual molecules, decipher the spatial resolution of gene transcripts, examine single cells, and study entire tissues and whole organisms. This approach ensures that scientists at the Malaghan Institute and throughout New Zealand can leverage advanced tools without needing to reinvent the wheel or secure elusive funding. By facilitating access and support, we are collectively pushing the sector forward and enhancing the overall impact of medical research.

"By integrating these various levels of analysis and leveraging data science to synthesise the findings, we help researchers understand the broader context of their studies. This holistic approach not only enhances the depth of scientific insights but also accelerates the development of new treatments and cures for diseases."

IN FOCUS

Mapping the lung's fight – how the entire organ responds to infection

Rebecca Palmer is a PhD student investigating the lung's multi-faceted immune response to provide a holistic understanding of how the lung adapts to different types of infections.

"A lot of the research that has been conducted both here at the Malaghan Institute and globally is related to specific cells within the lung and how they respond to infections," says Rebecca.

"My project is looking at the lung as a whole to understand how this complex organ defends itself in infections."

Our lungs are the surface of gas exchange in the body. Oxygen from the air we breathe in is absorbed, while carbon dioxide and water are breathed out. With its extensive branching structures, folded compactly between our ribcage, the total surface area can be as much as 140m2. That's a total area equivalent to a 2-bedroom house!

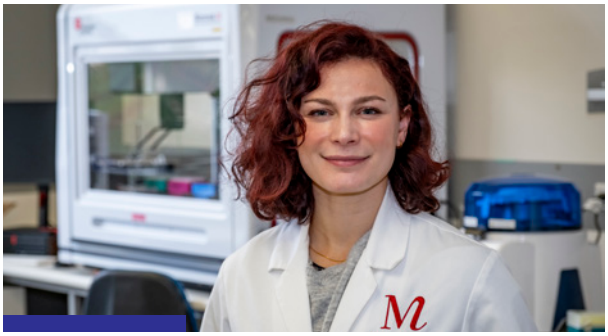
"As you can imagine, an area this large in our bodies that comes into direct contact with the air we breathe can make us vulnerable to attack from invisible threats like viruses and bacteria. My project will look at responses in the lungs to viral influenza infection and parasitic hookworm infection," says Rebecca.

Rebecca's PhD research aims to map out what the distinct immune responses are on a molecular, cellular and tissue level.

"Currently I'm developing the techniques to measure a broad range of parameters to give us an idea of what's happening on a whole-organ level."

As her research progresses, Rebecca and her team, led by Dr Kerry Hilligan, also want to understand how the lung deals with concurrent infections.

"How do the lungs respond to two different infectious agents acting at once? Does response to one threat help overcome another completely different type of threat?"



▲ Rebecca Palmer

Hailing from Palmerston North, Rebecca always loved science as well as theatre.

"Pursuing both science and theatre meant I could satisfy both my analytical, technical side and my creative, extroverted side."

At the end of high school, she had to make the tough decision to do one or the other. After considering joining a theatre company on a cruise ship, she eventually decided to go to Te Herenga Waka – Victoria University of Wellington to pursue an undergraduate and then a Master's in Biotechnology.

"Once I started my course, I couldn't imagine doing anything else. Biotechnology is such a broad field with so many potential applications, it was here that immunology captured my interest."

Before and after coming to work on her PhD at the Malaghan Institute, Rebecca squeezes in time to lead high-octane group fitness classes as an instructor at Les Mills gyms.

"For me being a fitness instructor is a way to satisfy my extroverted side, it taps into my love for theatre and ensures that part of me stays alive," says Rebecca.

"Conducting medical research and being a fitness instructor is incredibly rewarding because both activities, though completely different, have the potential to improve people's quality of life."

In Focus is a monthly e-update taking a close up look at our research and the scientists behind it. If you're not already subscribed, you can sign up on our website **malaghan.org.nz**

IN THE COMMUNITY

WENDY WALKER
Head of Fundraising

We had a wonderful time visiting supporters in Hawke's Bay this June, providing a research update in an exciting new format.

A huge thank you to Lexus of Hawke's Bay for hosting the event, and to our local Trust Board member Tony Mossman and the Friends of Hawke's Bay for putting together such a fantastic evening.

Our ambassador, David Downs, did a stellar job as MC, while Prof Graham Le Gros and Prof Kjesten Wiig engaged the audience with an insightful discussion on all things CAR T-cell therapy.

It's always a privilege to connect with our community, raise awareness about our research and gather the vital funds needed to accelerate our work. Together, as Team Malaghan, we're bringing better treatments and cures to New Zealanders.

We will hold similar events in Auckland, Wellington and Taupō over the next few months. Please get in touch if you'd like to receive information about future events.

▲ Malaghan Ambassador David Downs entertains our Hawke's Bay supporters

Chubb Life's June Challenge: wellness and wall sits

We were thrilled to see our charity partner, Chubb Life, take on a health challenge in June that was both fun and impactful. The Chubb social committee launched a nationwide wall-sit challenge, and everyone jumped in—quads burning, smoothies and juices in hand!

Teams across the country, including those working from home, embraced the challenge by turning it into a wellness day, complete with spa treatments, chair massages, and meditation sessions to keep everyone feeling zen. Immunity bundle prizes were awarded to the top contenders, highlighting their epic efforts and creativity.

In recognition of everyone's hard work, the Chubb Life Gives Back committee made a fantastic $2,500 donation to support Immune June.

We're incredibly grateful for this generosity, thank you, Chubb Life, for showing us the power of creativity and determination!

A heartfelt thanks to the Rotary Club of Upper Hutt

The Rotary Club of Upper Hutt has shown incredible community spirit by matching the $4,500 raised by club member Kevin Alkema, his friends, and his family.

This generosity was sparked after Dr Rachel Perret's inspiring presentation on the CAR T phase 2 trial at their meeting in June. Her insights left everyone hopeful for the future of medical research and cancer treatment here in New Zealand.

We cannot express enough gratitude for this wonderful support. Our community support brings us closer to groundbreaking advancements in cancer treatment, and it shows just how powerful community efforts can be.

Thank you to Kevin, the Rotary Club of Upper Hutt, and everyone involved for your commitment and generosity. Your support makes a tremendous difference!

▲ Chubb Life Auckland team focusing on their wall sit challenge for Immune June

▲ An-Li Theron and Dr Rachel Perret from the Malaghan with the Upper Hutt Rotary Club's Phill Newborn and Kevin Alkema.

Why a legacy gift matters for medical research

Medical research takes time. It can take decades for a breakthrough made in the lab to become a life-saving treatment. It requires vision, careful planning, secure funding and unwavering dedication to ensure that discoveries made today become future treatments and cures.

This is why legacy gifts are vital to transforming discoveries into cures. They provide the necessary momentum and sustainability to fuel our research, ensuring we don't waste any of its potential.

Legacy gifts help fund ground-breaking research and support the next generation of scientists and researchers.

"Gifts in wills enable us to do work that is otherwise difficult to fund, such as taking our science discoveries into the clinic for the benefit of New Zealand patients".

PROFESSOR FRANCA RONCHESE

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PLEASE CONTACT US IF YOU HAVE ANY QUESTIONS OR WOULD LIKE TO DISCUSS A LEGACY GIFT.

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Together we can harness the power of the immune system and save lives.

People we love are suffering and dying from diseases we don't know enough about. But we do know the immune system holds the key to prevention, treatment and cures. By supporting the Malaghan Institute you are providing hope to those living with disease now and in the future.

DEEPER UNDERSTANDING

We research how to use the immune system to fight disease.

BETTER TREATMENTS

We develop new immunotherapies to more effectively treat disease.

FAIRER ACCESS

We are committed to developing treatments that are affordable and accessible to all.

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If you would prefer, you can also donate via direct deposit in to our bank account.

If you donate via direct deposit, please email us with your details so we can say thank you and provide you with a donation tax receipt.

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