Leading in clinical trials

Delivering real-world impact
Clinical research is central to patient care at The Alfred, where leading practitioners who are also leading researchers care for the state’s most complex patients through its 14 statewide services. We are committed to partnering with industries and organisations specialising in clinical trials and research. To do so we have built strong relationships with universities and medical research institutes on The Alfred precinct; streamlined ethics and contracting processes, and built leading technology platforms. Our relationship with Nucleus Network, Australia’s largest phase 1 clinical trials facility, is key. The flow from Nucleus Network through to the clinical space means that the quantity and quality of pharmaceutical clinical trials that take place at The Alfred is unique.

Professor Stephen Jane
Director of Research, Alfred Health

Leading the way in clinical trials

"we offer the opportunity to progress from first-in-human to first-in-disease at the one site."

Clinical trials expertise

- Proven expertise in clinical trials
- Effective ethics approvals
- Efficient contracting
- Access to a growing & complex population
- First-in-human trial experts
- The right technology platforms

Clinical trials at The Alfred

- 1,500+ researchers
- >$100m in external research funding
- 377 currently open clinical trials
- 1,972 publications for researchers on this site
- 206 of the clinical trials commercially sponsored
The Alfred: serving all Victorians

The Alfred is an Australian leader in healthcare, treating the most critical and complex patients from across the state. It is home to one of the busiest Emergency and Trauma Centres in Australasia and the largest Intensive Care Unit in Victoria.

The Alfred provides healthcare to its primary catchment in Melbourne’s inner south and supports all Victorians through our 14 statewide services.

The Alfred’s strength lies in its dedicated workforce of leading clinical experts, who are consistently pursuing new treatments and models of care to deliver the best outcomes for their patients and communities.

It is also home to a community of leading researchers and practitioners focused on solving the world’s most critical health challenges.

Facts about The Alfred

- 89,075 patient admissions
- 65,000+ presentations to Emergency Department
- 11,600+ episodes of elective surgery
- 7,700 episodes of emergency surgery
- 8,000+ trauma patients
- 137,390+ appointments of specialist outpatients
- 700+ beds
- 6,650 staff

Leading in clinical trials | Real-world impact
Nucleus Network

Australia’s largest Phase 1 Clinical Trials Facility

Nucleus Network has an international reputation for excellence and is the preferred Australian provider for large-scale, phase 1 healthy volunteer and first-in-human clinical trials.

Its location at The Alfred precinct allows strong collaborative links with hospital-based investigators and clinical researchers.

Nucleus Network conducts approximately 50 Phase 1 clinical trials every year, with 20-25 of these being first-in-human.

The company services global pharmaceutical and biotechnology companies (80 per cent biotech; 20 per cent pharma), with the majority of customers based in the US (76 per cent) and others spread throughout Asia, Europe and Australia. In 2017, the facility expanded its capacity to 80 beds and added an internal pharmacy with a view to expanding the customer base, particularly in China and South Korea.

Nucleus Network brings together professionals with diverse experience working in the clinical trials industry in Europe and the US.

Streamlined ethics and governance

The Alfred Hospital Ethics Committee is a National Health and Medical Research Council (NHMRC)-registered and certified human research ethics committee, undertaking ethical reviews for all research undertaken on the precinct.

Importantly, it also reviews applications for any site participating in the Victorian or national ‘single ethical review’ scheme.

This streamlining enables research to undergo one ethics approval process with approval granted for all sites.

Clinical trials are supported by smooth and efficient contracting, using approved Medicines Australia or Medical Technology Association of Australia standard agreements. Flexibility is built into contracts with the ability to respond to individual trials.

For more: alfredhealth.org.au/research/ethics-research-governance

“Nucleus Network conducts approximately 50 Phase 1 clinical trials every year, with 20-25 of these being first-in-human.”
Clinical trials provide an excellent conduit for patients with life-threatening conditions to access potentially life-saving and costly medical therapies well in advance of their availability through current government subsidised schemes.

First-in-human trials of this type are rarely conducted anywhere else in the world.

Professor Kaye’s research has been directed towards characterising the pathophysiology of heart failure, with a particular emphasis on the identification of novel mechanisms that can be targeted for therapeutic intervention. Professor Kaye has been highly successful in generating intellectual property leading to commercial and clinical outcomes.

Professor Kaye received the Eric Sussman and RT Hall Prizes for research excellence from the College of Physicians and Cardiac Society. He was awarded the 2012 Eureka Prize for Medical Research Translation.

MOST SIGNIFICANT TRIAL
A novel formulation of a drug used to treat advanced heart failure, now tested in over 40 patients with severe symptoms.

Cardiology

Professor David Kaye
- Director, Department of Cardiology, The Alfred
- NHMRC Principal Research Fellow
- Head of Cardiology Division at the Baker Heart and Diabetes Institute
- Adjunct Professor, Monash University

“First-in-human trials of this type are rarely conducted anywhere else in the world.”

Professor Kaye’s research has been directed towards characterising the pathophysiology of heart failure, with a particular emphasis on the identification of novel mechanisms that can be targeted for therapeutic intervention. Professor Kaye has been highly successful in generating intellectual property leading to commercial and clinical outcomes.

Professor Kaye received the Eric Sussman and RT Hall Prizes for research excellence from the College of Physicians and Cardiac Society. He was awarded the 2012 Eureka Prize for Medical Research Translation.

MOST SIGNIFICANT TRIAL
A novel formulation of a drug used to treat advanced heart failure, now tested in over 40 patients with severe symptoms.

Gastroenterology

Professor Stuart Roberts
- Head of Hepatology and Consultant Gastroenterologist, The Alfred
- Adjunct Clinical Professor of Gastroenterology, Monash University
- Chairperson, ALA Clinical Research Network

“Clinical trials provide an excellent conduit for patients with life-threatening conditions to access potentially life-saving and costly medical therapies well in advance of their availability through current government subsidised schemes.”

Having completed a Hepatology Fellowship at the Mayo Clinic in the USA, Professor Roberts was awarded a Doctorate of Medicine by the University of Melbourne for his liver research. More recently, he completed a Master of Public Health at Monash University with High Distinction. His main research interests are hepatocellular carcinoma, viral hepatitis, autoimmune hepatitis, fatty liver disease, and non-invasive markers of liver disease. He has been principal investigator in over 165 sponsored and investigator initiated clinical trials from phase I-IV.

Professor Roberts has published more than 170 original articles across a range of high-impact journals including the New England Journal of Medicine, Lancet, Annals of Internal Medicine, Gastroenterology, Gut, Hepatology, and Journal of Hepatology.

MOST SIGNIFICANT TRIAL
The Phase III randomised controlled trial of Sofosbuvir and Velpatasvir in patients with chronic hepatitis C genotype 3 infection. This was published in the New England Journal of Medicine and is now the standard of care for the vast majority of patients with chronic hepatitis C.

“Clinical trials provide an excellent conduit for patients with life-threatening conditions to access potentially life-saving and costly medical therapies well in advance of their availability through current government subsidised schemes.”
Clinical trials give patients and their families therapeutic options – hope for extending survival – that would otherwise not be available.

After completing doctoral studies at the Walter and Eliza Hall Institute of Medical Research in 2005, Dr Wei joined The Alfred in 2008 to develop the Acute Myeloid Leukaemia (AML) research program. He has been the AML disease group chairperson for Australasian Leukaemia and Lymphoma Group since 2009 and has led multiple nationwide cooperative group studies as chief investigator.

Dr Wei is an executive member of the ALLG Scientific Advisory Committee, and a member of the National Medical and Scientific Advisory Committee of the Leukaemia Foundation of Australia. He sits on the International Steering Committee for Celgene, providing expert advice on AML. To enhance translational research, Dr Wei has established the Alfred Haematology Tissue Bank, the diagnostic molecular haematology laboratory and a pre-clinical research laboratory to focus on the role of targeting survival pathways in AML.

The Alfred has made a significant impact in positioning a new class of drugs called BH3-mimetics, designed to promote cancer cell death, to treat patients with AML. The Alfred has conducted a number of clinical trials (phase 1b-3) in collaboration with Abbvie which has resulted in highly promising outcomes for elderly patients with AML. Pivotal studies are underway to determine whether venetoclax in combination with low-dose chemotherapy will become the new standard of care for elderly AML.

Professor Spencer completed his medical training in clinical and laboratory haematology in 1992. Subsequently, he was awarded a LRF Fellowship and spent three years at the Royal Postgraduate Medical School in London, where he undertook research into B-cell clonality in chronic myeloid leukaemia and was awarded a Doctorate of Medicine from the University of London. Professor Spencer moved to The Alfred in 1999, where he established an independent translational research program. He also established a first-in-human and early phase haematology clinical research unit.

Professor Spencer serves on the scientific advisory boards of the International Myeloma Foundation (IMF), International Myeloma Working Group (IMWG) and the European Myeloma Network (EMN). He is a Director of the Australasian Leukaemia and Lymphoma Group (ALLG) and the International Myeloma Society (IMS). He is the immediate past-President of the Haematology Society of Australia and New Zealand (HSANZ).

The ALLG MM17 trial for myeloma patients who fail to respond to standard treatment. This group of patients has historically had poor survival rates. Professor Spencer’s approach exploring the use of Kyprolis and thalidomide has demonstrated very high response rates, including patients becoming minimal residual disease (MRD) negative.

“Clinical trials give patients and their families therapeutic options – hope for extending survival – that would otherwise not be available.”

Haematology

Doctor Andrew Wei
- Chairperson AML disease group Australasian Leukaemia and Lymphoma Group
- Haematologist & Head of Leukaemia Research, The Alfred
- Victorian Cancer Agency Research Fellow
- Adjunct Associate Professor, Australian Centre for Blood Diseases

Professor Andrew Spencer
- Director of the Australasian Leukaemia and Lymphoma Group
- Head of the Malignant Haematology and Stem Cell Transplantation Service, The Alfred
- Professor of Haematology, Monash University
- Head of the Myeloma Research Group, Australian Centre for Blood Diseases
Infectious diseases

Professor Jennifer Hoy
- Professor Director of HIV Medicine at The Alfred and Monash University

“My passion is now concentrated on ensuring the quality of care – and the quality of life – provided to people living with HIV.”

Professor Hoy has over 30 years’ experience in HIV clinical research and patient care, and established the Clinical Research Unit at The Alfred Hospital. Prior to this, she established and directed the Infectious Diseases Clinical Research Unit from 1999-2008, building it into an internationally recognized research program. She has been Principal Investigator for over 175 clinical studies at The Alfred and has collaborated widely on investigator-initiated pathogenesis studies. Professor Hoy has been co-principal investigator on five large studies investigating ARV therapy and bone loss, including the SMART and START studies on which she was the Principal Investigator for Australia. Professor Hoy has been a productive member of the IAS-USA Antiretroviral Guidelines Panel since 2012. Her current research interests include the comorbidities associated with ageing and HIV, especially bone and cardiovascular disease, and finding better ways to prevent and manage them.

MOST SIGNIFICANT TRIAL
The START international study recruited 4500 people globally and demonstrated that starting treatment for HIV infection soon after diagnosis provided survival benefits in addition to reduction in AIDS and non-AIDS diseases. The results of this trial provided the gold standard evidence to change all antiretroviral guidelines throughout the world in 2015.

Medical Oncology

Professor Mark Shackleton
- Director of Oncology, The Alfred
- Professor of Oncology, Monash University
- Victorian Cancer Agency Clinical Research Fellow
- Chair, Australian and New Zealand Melanoma Trials Group

“The efficacy of most major advances in cancer treatment was first demonstrated in clinical trials. These trials often provide early access for patients to emerging and sometimes life-saving treatments.”

After training in medical oncology at the Ludwig Institute in Melbourne, Professor Shackleton undertook PhD studies at the Walter and Eliza Hall Institute of Medical Research and post-doctoral work at the University of Michigan, USA. He has consistently published in the world’s top medical and scientific journals. Professor Shackleton has received several major prizes for his research, including the 2006 Victorian Premier’s Award for Medical Research, a 2010 NHMRC Achievement Award, a 2011 Pfizer Australia Fellowship, and a 2016 Victorian Cancer Agency Clinical Research Fellowship. In 2012, he was awarded the Australian Science Minister’s Prize for Life Scientist of the Year.

SIGNIFICANT TRIALS
The Alfred Oncology Unit has been a key player internationally in conducting clinical trials, particularly in melanoma and brain cancer, contributing substantially to key findings published in leading journals such as the New England Journal of Medicine.
Professor O’Brien is a specialist in neurology and clinical pharmacology, with particular expertise in epilepsy and related brain diseases, including traumatic brain injury, brain tumours and neurodegenerative diseases, neuropharmacology and in-vivo imaging in animal models and humans. He was formerly The University of Melbourne’s James Stewart Chair of Medicine and Head of the Department of Medicine at the Royal Melbourne Hospital (2008-17). He leads a large translational research team focused on improving treatments for people with epilepsy and related brain diseases. Professor O’Brien’s research has two primary goals: firstly, to better understand the determinants of treatment response, identify biomarkers for treatment outcomes, and develop new treatment approaches. Secondly, to investigate the fundamental neurobiological basis, and inter-relationship, of the neuropsychiatric co-morbidities present in many patients with epilepsy and neurodegenerative conditions. He has been a Principle Investigator in more than 100 commercially sponsored and investigator initiated trials, and is Chair of the Australian Epilepsy Clinical Trials Network (AECTN).

MOST SIGNIFICANT TRIAL
The STAR 1 trial (2016-18), for which Professor O’Brien was the Principle Investigator, was the first double-blinded randomised control trial of a cannabinoid treatment for adults with drug resistant focal epilepsy. It was also the first to trial a novel transcutaneous delivery system that avoided many of pharmacokinetic and side-effects issues with oral cannabinoid treatments. The study involved 188 participants and 14 trial sites across Australia and New Zealand, coordinated by the AECTN Chair Professor O’Brien-Chairs. The results of the study showed that the treatment was well tolerated, with excellent patient compliance and acceptance, establishing the viability of the transdermal treatment approach. Continued open-label treatment in STAR 2 showed sustained clinically meaningful reductions after 6 & 12 months of treatment.

At The Alfred, we are conducting a number of world first, early phase, trials in Australia’s only dedicated Neurology Trials Unit. We are investigating whether new treatment approaches, derived from the paradigm-shifting advances in translational neuroscience research, can for the first time successfully treat these incurable brain diseases.

Professor Kulkarni directs a large psychiatric research group, the Monash Alfred Psychiatry Research Centre (MAPrc), which is dedicated to discovering new treatments, new understanding and new services for people with a range of mental illnesses. She became a Fellow of the Royal Australian and New Zealand College of Psychiatrists in 1989 and was awarded a PhD from Monash University in 1997 for her thesis “Women and Psychosis”. She is internationally acknowledged as a leader in the field of reproductive hormones and their impact on mental health. Professor Kulkarni was elected the President of the International Association of Women’s Mental Health in 2017.

MOST SIGNIFICANT TRIAL
Pioneering the use of Estradiol for treatment-resistant schizophrenia: a large-scale randomized-controlled trial in women of child-bearing age.

Clinical trials allow rapid translation of research into patient care and in psychiatry, that is urgently needed. I am aiming to enhance women’s mental health by developing new treatments for mental illness.

Professor Terence J. O’Brien
MB, BS, MD, FRACP, FRCPE, FAHMS, FAES
- Program Director Alfred Brain, Director of Neurology, and Deputy Director of Research, Alfred Health
- Van Cleef Roet Professor of Medicine (Neurology), Monash University, Head, Departments of Neuroscience and Medicine, Monash University
- Chair, Australian Epilepsy Clinical Trials Network (AECTN)

Professor Jayashri Kulkarni
- Professor of Psychiatry, The Alfred and Monash University

Neurology

Psychiatry
Contact

**Alfred Research**
The Alfred Centre, 6/99 Commercial Road
Melbourne VIC 3004
T: + 613 9903 0640
E: alfredclinicaltrials@alfred.org.au

**Nucleus Network**
Burnet Tower, 5/89 Commercial Road
Melbourne, Vic 3004
T: + 613 8593 9800
F: + 613 9076 8911
E: businessdevelopment@nucleusnetwork.com.au

Front cover image credit: ASPREE (ASPirin in Reducing Events in the Elderly) Clinical Trial,
School of Public Health and Preventive Medicine,
Monash University.