



CCRE
THERAPEUTICS

Organisation Profile





mission

CCRE – Therapeutics' mission is to improve clinical outcomes at the individual and community level through the use of evidence, based on high quality clinical research

background

In 1997, the Centres of Clinical Excellence in-hospital-based research program was initiated by the Federal Government. 2002 saw the extension of this activity to include Centres of Clinical Research Excellence (CCRE).

The Department of Epidemiology and Preventive Medicine was successful in establishing a CCRE in Therapeutics under the direction of Professors Henry Krum, John McNeil, Andrew Tonkin, Andrew Forbes, Paul Myles and Flavia Cicuttini.

CCRE – Therapeutics: strategic areas

At CCRE – Therapeutics our expertise in epidemiology, clinical trials, research education, clinical pharmacology, data management and statistics to provide research excellence in three key areas;

- Clinical Research
- Clinical Outcomes Registers
- Translational Research



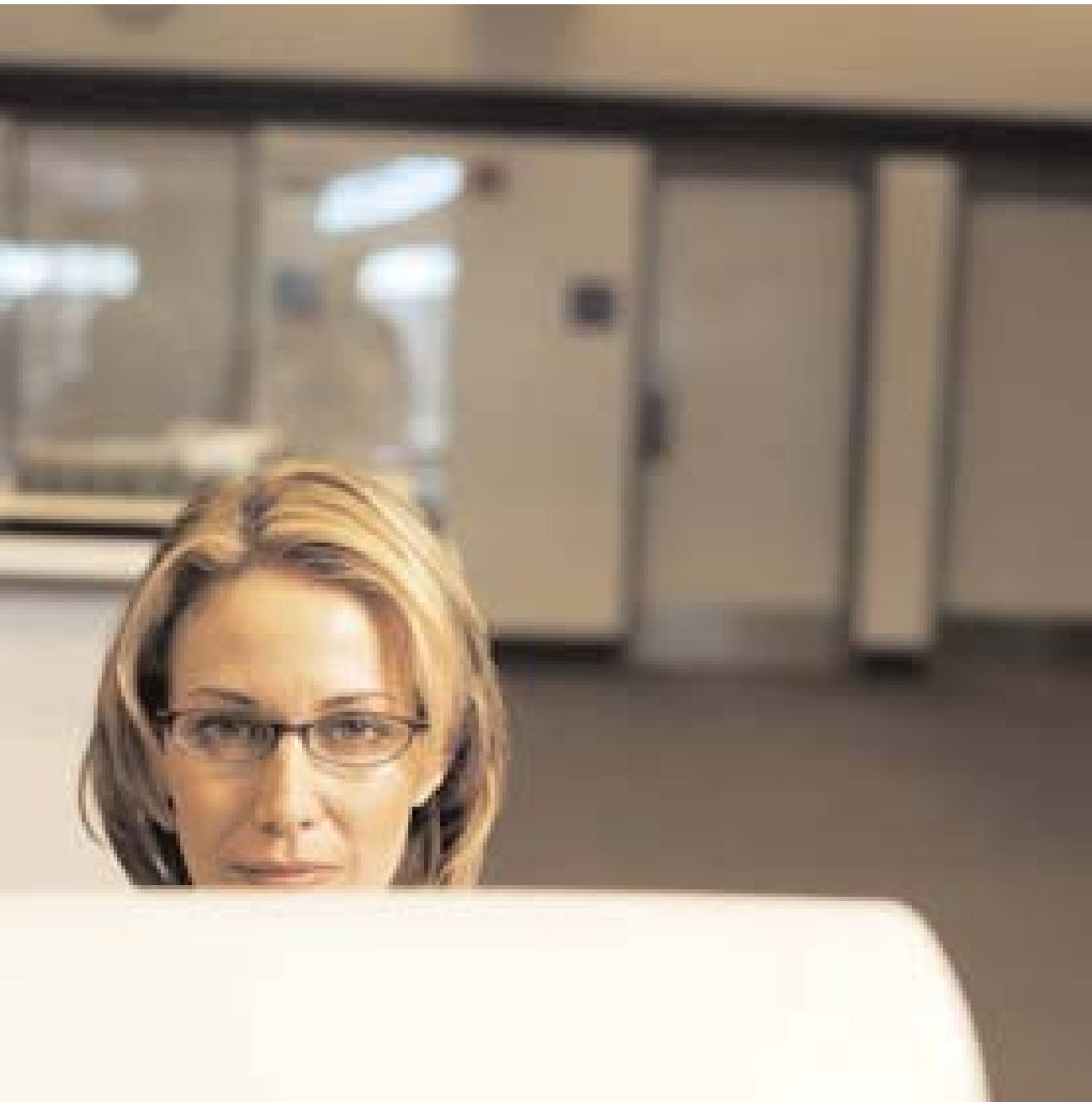
clinical research

we have a dedicated clinical research facility and direct access to the state-of-the-art early-phase clinical research centre at the Alfred Hospital

Our clinical research capabilities are based around the disciplines of epidemiology, clinical pharmacology, clinical trials, data management and bio-statistics. We have a particular interest in chronic disease research, including cardiovascular and musculoskeletal diseases, and surgical research. CCRE – Therapeutics has direct access to the state-of-the-art early-phase clinical research centre (Alfred/Baker/Monash Centre for Clinical Studies) at the Alfred Hospital, directed by Professor Henry Krum.

Our Senior Academics have had leading roles as study chairpersons and principle investigators in major clinical outcome studies including:

- LIPID Study (5 year follow-up of 6000 patients)
- ANBP2 – 2nd Australian National Blood Pressure Study (6000 patient, 5-year study through network of 103 General Practitioners)
- UNIVERSE Study - Statin therapy in heart failure
- CHABLIS Study - Optimal RAAS blockade in chronic heart failure



clinical outcomes registries

our capabilities in the area of clinical research outcomes registries are supported by our extensive experience in large scale data management and bio-statistical analysis

The capabilities of CCRE – Therapeutics in the area of clinical research outcomes registry management and research is demonstrated by our extensive experience in large scale data management and bio-statistical analysis. Key staff in this area include:

- A/Prof Christopher Reid who has established registers in cardiothoracic surgery and pharmacological drug therapy.
- A/Prof Andrew Forbes who has over 15 years experience in bio-statistics and clinical trial design.
- Mr Adam Meehan, previously data manager for the AusDiab-Longitudinal epidemiological study, currently manages the ASPREE Data Centre.

translational research

patient care and outcomes
are significantly improved when
knowledge gained from research
is translated into clinical practice

Our translational research activities focus upon the development of strategies to enhance the uptake of evidence based management in clinical practice, and achieving research outcomes which inform health policy development.

We have a major interest in the development of methodology for the uptake of evidence-based therapeutic management at both the specialist and general practice level. CCRE – Therapeutics' lead investigators have extensive experience as members of guideline committees, and have developed tools for use in general practice and community settings to improve patient management and clinical outcomes.

CCRE – Therapeutics can provide clinical and data management expertise to develop evidence-based clinical management programs for community organisations, general practitioners, non-government organisations and industry.



clinical opinion leaders

ccre researchers

Professor Henry Krum **Director, CCRE – Therapeutics**

Professor Henry Krum is a well recognised figure in cardiovascular clinical pharmacology and therapeutics, attested to by his extensive professional activities in this area. Prof Krum is also a physician at the Alfred Hospital in Melbourne and heads Clinical Pharmacology at Monash University and the Alfred Hospital. His interests lie with heart failure and hypertension, and his work spans the fields of basic, clinical and applied sciences.

Prof Krum has been a member of many International Steering and Executive Committees for major clinical trials in the area of cardio-vascular pharmacotherapy. He currently leads a number of multicentre investigator-initiated trials testing cardiovascular therapeutic strategies.

A/Prof Christopher Reid **Associate Director, CCRE – Therapeutics**

A/Prof Reid is an epidemiologist with a background in exercise physiology. He has extensive experience in management of large-scale clinical studies and data registries, and was Study Director for the 2nd Australian National Blood Pressure Study. His research focus in recent years has been in the area of evidence-based management for primary and secondary prevention of cardiovascular disease.

A/Prof Reid directs the Data Management area of CCRE – Therapeutics, and is chief investigator on a number of large-scale longitudinal clinical studies and patient registries.

Professor John McNeil **Chief Investigator, CCRE – Therapeutics**

Prof John McNeil (MBBS, MSc, PhD, FRACP, FAFPHM) is a clinical pharmacologist and epidemiologist who heads the Department of Epidemiology and Preventive Medicine at Monash University. Prof McNeil provides CCRE – Therapeutics with leadership and expertise in the application of epidemiology to the study of drug efficacy, safety and cost-effectiveness. He leads CCRE – Therapeutics' Translational Research program and has research interests in studies of drug safety and epidemiological modelling.

Professor Andrew Tonkin **Chief Investigator, CCRE – Therapeutics**

Prof Andrew Tonkin (MBBS, MD, MRACP, FRACP) has a long-standing interest in clinical research particularly in the area of cardiology. Prof Tonkin is Director of the National Heart Foundation of Australia and Adjunct Professor in Preventive Cardiology at Monash University. Prof Tonkin provides CCRE – Therapeutics with expertise in the design and analysis of small-scale and large-scale randomized therapeutic trials.

A/Prof Flavia Cicuttini **Chief Investigator, CCRE – Therapeutics**

A/Prof Cicuttini heads the Clinical Diagnostic and Chronic Diseases Unit within the Department of Epidemiology and Preventive Medicine, Monash University. A/Prof Cicuttini has research interests in the development and validation of clinical outcome measures in clinical studies, especially in the development of methods for quantifying disease progression in degenerative joint disease.

Professor Paul Myles **Chief Investigator, CCRE – Therapeutics**

Professor Paul Myles is the Director of Anaesthesia and Perioperative Medicine at the Alfred Hospital, and Professor of Anaesthesia at Monash University. Prof Myles is involved in a number of large multi-centre trials aiming to improve outcomes after surgery and anaesthesia. These include an investigation of nitrous oxide in anaesthesia (the ENIGMA Trial), and aspirin with or without tranexamic acid in coronary artery surgery (the ATACAS Trial).

A/Prof Andrew Forbes **Chief Investigator, CCRE – Therapeutics**

A/Prof Forbes provides biostatistical expertise and professional leadership to CCRE – Therapeutics. He worked in the pharmaceutical industry in the US, before joining Monash University to head one of the largest biostatistical units in Victoria, in the Department of Epidemiology and Preventive Medicine.

Dr Danny Liew **Associate Investigator, CCRE – Therapeutics**

Dr Danny Liew (FRACP, PhD) is a clinical pharmacologist whose research interests lie in pharmacoepidemiology and pharmaco-economics. His work involves translating evidence from clinical and population-based studies for application to clinical and public health practice and health policy.

Dr Andrew Ajani **Associate Investigator, CCRE – Therapeutics**

Dr Andrew Ajani is Director of Coronary Care at the Royal Melbourne Hospital. Dr Ajani's research interests lie in interventional cardiology and he is the convener of the Melbourne Intervention Group, who have established a large registry of coronary interventional procedures managed through the CCRE – Therapeutics Data Centre.

Professor Frank Rosenfeldt **Associate Investigator, CCRE – Therapeutics**

Professor Rosenfeldt leads the Cardiac Surgical Research Unit at the Alfred and Baker Medical Research Unit. Prof Rosenfeldt has research interests in nutritional supplementation and cardiac function. His research is aimed at improving the success of procedures such as cardiac bypass and angioplasty.

A/Prof John Amerena **Associate Investigator, CCRE – Therapeutics**

A/Prof Amerena is a cardiologist at Geelong Hospital and senior academic in the Department of Clinical and Biomedical Sciences at University of Melbourne. A/Prof Amerena has broad research interests in clinical cardiology, and particular interest in coronary artery disease and hypertension management.

Dr Robyn Woods **Executive Officer, ASPREE**

Robyn Woods is a senior NHMRC Fellow at the Howard Florey Institute with research interests in cardiovascular physiology and the pathophysiology of cardiac natriuretic peptides.

Mr Adam Meehan **Data Manager, CCRE – Therapeutics**

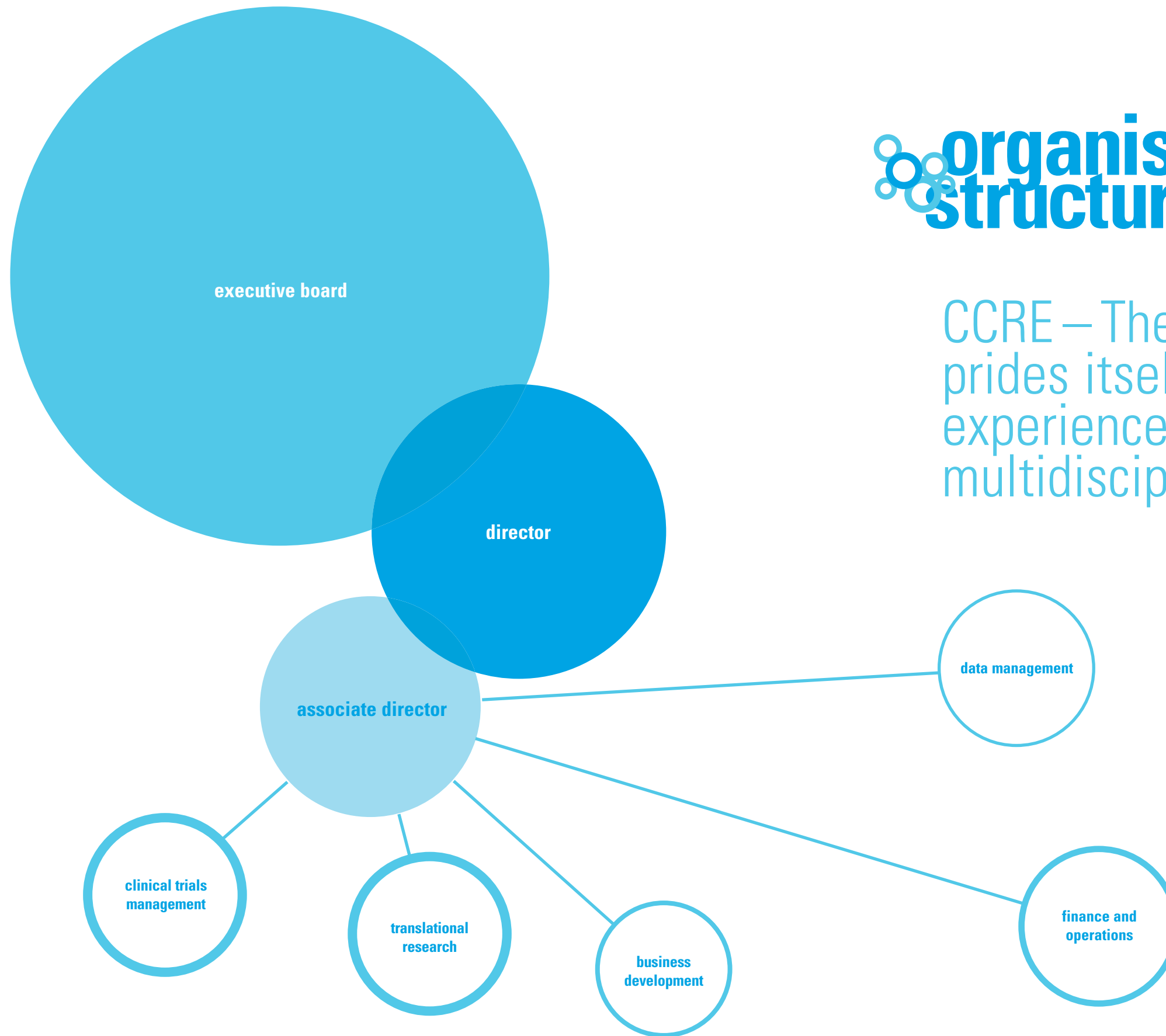
Adam Meehan brings to CCRE – Therapeutics expertise in the management of large epidemiological research databases and the implementation of state-of-the-art Health-IT technology.

Dr Alice Owen **Research Fellow, CCRE – Therapeutics**

Alice Owen is a physiologist with research interests in cellular lipid composition and oxidative stress in cardiovascular disease, obesity and diabetes.

organisational structure

CCRE – Therapeutics prides itself on having an experienced and motivated multidisciplinary team

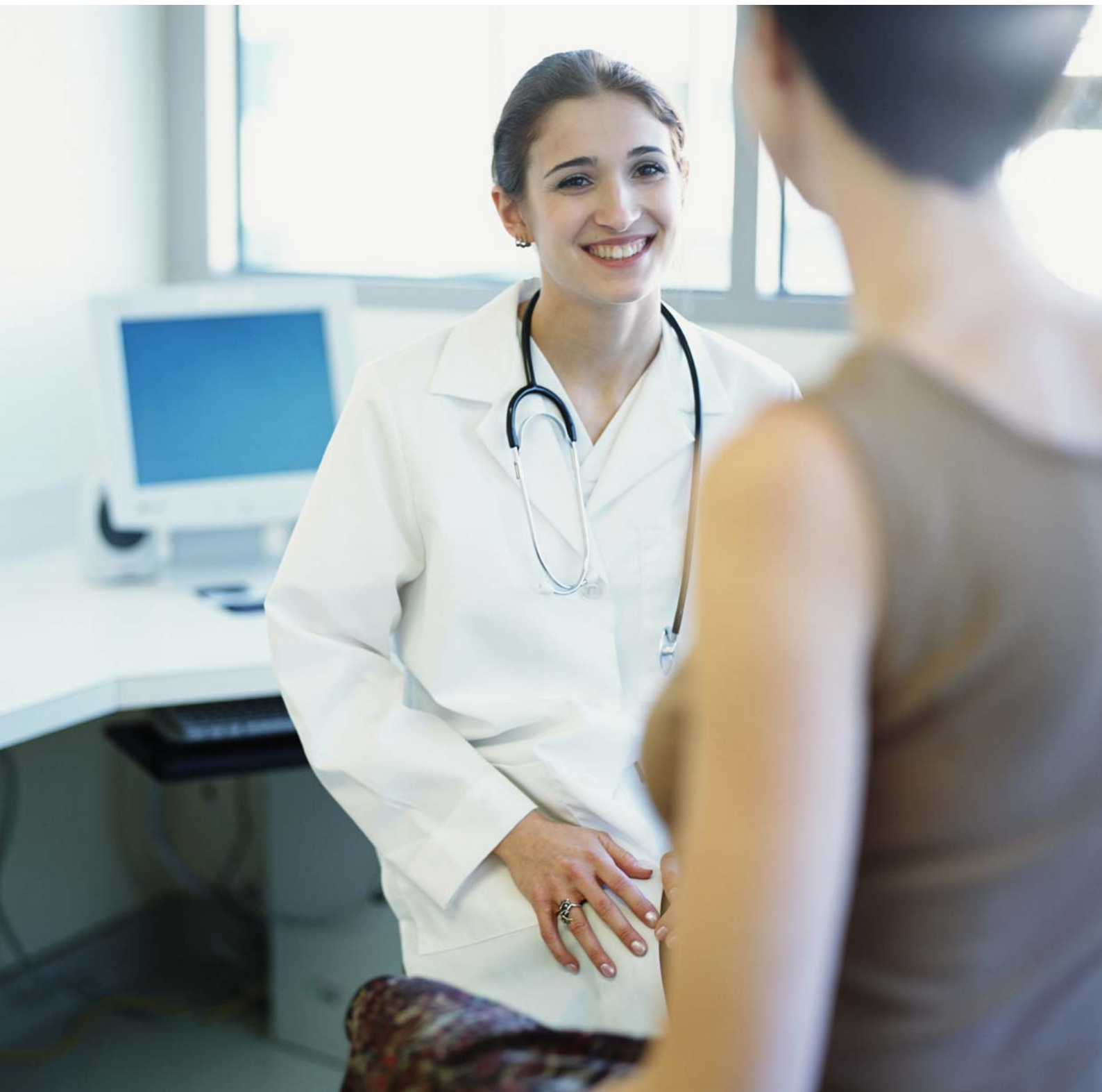




data management

we offer a range
of services to meet
the needs of our
clients and the
community

We have experienced data managers and bio-statisticians to assist in the development of case record forms and database design. We can provide manual, scan, fax, IVRS and internet based data capture methodologies that provide a full range of reporting services – regular monitoring of study recruitment progress and data query resolution. The CCRE Data Management Centre also provides comprehensive statistical analysis, a complete study report and manuscript preparation as an integral part of our services. Our data management services conform to GCRP standards.



clinical research network

specialist hospital networks and general practitioner networks with some 1000+ general practitioners across Australia are accessible to our research partners

We have extensive collaboration in both the specialist hospital and general practice setting. With these partners, we have successfully become the Australian co-ordinating centre for national and multi-national studies such as the 2nd Australian National Blood Pressure (ANBP2) Study, the Aspirin for Reducing Events in the Elderly (APSREE) Study, the REACH Study (an international prospective observational study of peripheral artery disease), and the UNIVERSE Study to name a few.



collaboration

collaboration enhances our capacity to undertake national and multi-national clinical research studies that help put Australia on the clinical research map

The CCRE – Therapeutics team have a wealth of experience in national and international joint initiatives and collaborations. CCRE – Therapeutics has established collaborative links with a number of research centres, including the following:

- Department of Medicine, St Vincent's Hospital, Melbourne
- Centre for Human Drug Research, Netherlands
- INCITE International Phase II Cardiovascular Group
- Baker Heart Research Institute, Melbourne
- Hanoi Heart Institute, Vietnam
- McMaster Cardiovascular Research Centre, Canada
- Central Drug Research Institute Lucknow, India
- George Institute, Sydney



CCRE

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