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End-to-end clinical trial capabilities

South Australia provides the fastest pathway for clinical trial conduct for submission to global regulatory agencies.

The unique Australian regulatory framework allows for rapid start-up time without compromises. South Australia's complete ecosystem delivers end-to-end across all elements of the supply chain, for trials of drugs, medical devices and digital health products.

The state's major hospitals have world-class infrastructure with dedicated clinical trial units allowing for access to dedicated investigators committed to clinical research.

South Australia is an ideal location for clinical trials for both healthy individuals and patients including specialised patient populations.

Our collaborative ecosystem connects deep clinical research, manufacturing and an end-to-end clinical trial supply chain with world-class infrastructure and digital capabilities for drug development, advanced manufacturing and health innovation.

As a strategic entry point for exploring the Australian trials sector, our expertise provides an efficient pathway to clinical trial conduct.

Fast and trusted for global markets (including FDA, EMA, TGA), working in South Australia will help you start your clinical trials in as little as six weeks.

Start in South Australia to leverage the Australian Advantage

SPEED

- Efficient regulatory framework saves up to one year in regulatory timelines.
- Investigational new drug application (IND) not required for Phase I.

OUALITY

 Globally accepted data with the highest quality standards for submission to regulatory agencies including the US FDA, UK MHRA, EU EMA, and Japan PDMA.

VALUE

43.5% R&D tax incentive.

South Australian Advantage

Australia's most experienced providers operate in South Australia, creating the nation's most comprehensive, connected and supportive clinical trial ecosystem, providing support across the entire supply chain:

- Local ethics approval and an advanced ecosystem allows you to start trials in five to six weeks.
- Save by collaborating with experienced partners, providing specialist advice for you to operate efficiently, de-risk and add value to your trial exploration, setup and conduct.

The globally unique ecosystem provides a trusted and connected environment for you to partner and innovate, maximising value for your organisation.

Connected health innovation

Data-driven and precision health innovation

Adelaide is home to world-leading artificial intelligence and data analytics capabilities, supported by unique clinical infrastructure and datasets providing a location for cutting-edge clinical research and drug development.

The Australian Institute for Machine Learning (AIML) has globally ranked capability in artificial intelligence, machine learning, computer vision research and deep learning. AIML works with leading global companies including Roche, GSK, Medtronic and Siemens to push the frontier of precision health.

Connected innovation precincts

Adelaide's flagship precincts bring together worldclass researchers, companies, government, academia, infrastructure, investment, teaching and clinical care to create unique opportunities for innovation that underpins the state's leadership and strengths in health and medical sectors.

With Adelaide BioMed City, Tonsley and Lot Fourteen Innovation Districts connected and closely located, South Australia has a unique ecosystem where health and life science research, manufacturing and clinical care is deeply embedded with technology innovation.

Manufacturing capability

Australia's commercial drug manufacturing pedigree was forged in South Australia and features many of its leading academic manufacturing resources and long-established commercial operations.

Our contract development manufacturing organisations (CDMO) support accreditation for global regulators from R&D through to commercial scale, with capability and breadth across small and large molecules.

Adelaide is home to global operations for pharma and nutraceutical therapeutics, generics and supplement manufacturers.

Drug development and biotech

South Australia is a centre for drug research and new biomedical companies. Key opinion leaders focus on drug development across a wide range of specialisations including immunology, infectious diseases, neuroscience and endocrinology.

Oncology is a major focus, including precision health, Car-T technology, computational systems, epigenetics, single cell and spatial technologies, gene regulation, molecular signalling, translational oncology and cancer genomics.



Clinical trials: Connected health innovation



Complete clinical trial ecosystem

World's fastest regulatory framework for earlyphase clinical trials for submission to global regulatory agencies



World-class hi-tech capabilities

Artificial intelligence, augmented reality, virtual reality, quantum and data analytics leadership and top 6 in the world for computer vision research



State-of-the-art GMP manufacturing

R&D to commercial scale, small and large molecules and radiopharmaceuticals



43.5% R&D tax incentive

Supporting companies across R&D activities in Australia



World leader for personalised health innovation

Unique clinical data sets and top artificial intelligence talent developing next generation health innovation



World-class health and life sciences ecosystem

One of the largest and most technologically advanced in the southern hemisphere



Leader in cancer research, clinical translation and care

Including isotope synchrotron, proton therapy, key opinion leaders and research institutions



Advanced device manufacturing capabilities

Expertise and capability for ISO 13485



Leading biotech R&D

Concentration of world-class biotech including vaccine, microbiome and CarT-cell research







Key opinion leaders

World-leading medical researchers and clinicians are advancing global clinical research. In Australia, medical doctors usually practice across public hospitals, academia as well as private practice embedding a bed-to-bedside capability.

Dedicated principle investigators include:

Professor Helen Marshall MBBS, DCH, MPH, MD

Professor Marshall is a globally renowned medical researcher, who was awarded the South Australia 2022 Australian of the Year Award and the 2022 SA Woman of the Year Award.

Professor Marshall is a medical researcher specialised in vaccinology, immunology and infectious diseases. She has published over 230 peer-reviewed papers in general medicine and specialist journals across diverse disciplines with more than 8,000 individual paper citations.

Professor Marshall has been an investigator on over 107 implementation, clinical and epidemiological studies.

Professor Sepehr Shakib MBBS, FRACP, PhD

Professor Shakib is a clinical pharmacologist with appointments at the Royal Adelaide Hospital and CMAX Clinical Research, where he leads a group of twelve principal investigators.

Professor Shakib has been involved in over 250 Phase I clinical trials in a wide range of therapeutic areas. He is a recipient of multiple awards and grants and has over 100 publications.

Professor Paul Rolan MBBS, MD, FRACP, FFPM (UK), FFPMANZCA

Professor Rolan is a clinical pharmacologist, drug developer and pain management physician. His major clinical and academic interest is in chronic pain and headache, focusing on the development of biomarkers, evaluation of novel therapies and mechanisms of disease.

Professor Rolan has been principal investigator in over 750 clinical research studies and has been an active consultant, both to the pharmaceutical industry as well as an invited speaker to the FDA.

Professor Guy Ludbrook PhD, MBBS, FANZCA

Professor Ludbrook is a specialist anaesthetist.

His expertise includes neuropharmacology, medical devices, anaesthesia, clinical trials, anaesthetic and analgesic drugs, drug delivery and health services.

Professor Ludbrook has been principal investigator on many clinical trials, both commercial and investigator-initiated, and sits on data safety monitoring boards for multiple international clinical trials. He is increasingly involved in health services reviews to optimise value in healthcare, and in the design and the study of new systems of care.

Professor Maria Makrides BSc, BND, PhD, FAA, FAHMS, FNSA

Professor Makrides is an international leader in maternal-infant nutrition, with a focus on optimising the cognition, growth and immune development of children. She is especially recognised for her rigorous nutritional intervention studies during the first 1,000 days of life—between conception and a child's second birthday.

Professor Makrides is an elected Fellow of the Australian Academy of Science and the Australian Academy of Health and Medical Science and was awarded South Australian Scientist of the Year in 2022. She has over 300 peer reviewed publications.

Dr Paul Wabnitz BSc, MD, PhD, MBA, FRACP

Dr Wabnitz is a Consultant Physician, Clinical Pharmacologist, Toxicologist and Medical Oncologist.

Dr Wabnitz is qualified in regulatory submissions, Human Research Ethics Committee (HREC) reviews and approvals, clinical trial design and execution, medical monitoring and extensive clinical trial networks within Australia, Asia, Europe and the USA.

Dr Wabnitz has acted as a principle investigator and medical monitor on over 50 first in human Phase I/II clinical trials over the last two years, including several Phase I/II first-in-human oncology studies.

Professor Chris Sweeney MBBS, MD

Professor Sweeney is a medical oncologist with strong research interest in drug discovery and development.

Professor Sweeney's focus is on the management of genitourinary malignancies, particular prostate and testicular cancer.

Professor Sweeney is a highly active contributor in the field, with appointments at Harvard Medical School and previous appointment at Dana-Farber Cancer Institute.

Professor Sweeney has over 25 years experience in hematology and oncology and leading clinical trials as well as preclinical drug discovery and translational research. He has either led or contributed to over 300 peer-reviewed original research publications and is an experienced principal investigator.

Professor Chris Karapetis MBBS, MMedSci (Clin Epi), FRACP

Professor Karapetis is a medical oncologist known for his groundbreaking work on predictive biomarkers in gastro-intestinal malignancy.

He has established research interests in the areas of lung cancer, gastro-intestinal malignancy, molecular targeted therapies, predictive biomarkers, epidemiology, and clinical research methodology. He specialises in medical oncology and innovation in cancer.

Professor Karapetis has been the principal investigator on over 160 clinical trials and has published over 250 papers.

Professor Timothy P. Hughes MD, FRACP, FRCPA, MBBS, FAAHMS

Professor Hughes is a medical oncologist, specialising in chronic leukemias and myeloproliferative disorders.

Professor Hughes had a significant leadership role in the establishment of the molecular response criteria and kinase domain mutation screening guidelines that are used world-wide to monitor response and resistance in chronic myeloid leukaemia (CML).

Professor Hughes has been a principal investigator on many of the key Global and Australian CML trials that have shaped the way tyrosine-kinase inhibitors (TKI's) are selected and sequenced.

He has published over 300 papers with over 54,000 citations.

A/Professor Rohit Joshi MBBS, MD, FRACP, FACP, FRCP

A/Professor Rohit is a medical oncologist who treats all solid cancer types with major interests in lung, colorectal, pancreatic, renal, melanoma and breast cancers.

A/Professor Joshi's research areas included breast, lung, colorectal, melanoma, head and neck, genitourinary cancers and more, including Phase I, Phase II and Phase III studies.

Dr Ganessan Kichenadasse MBBS, FRACP, M Clin Edn, PhD

Dr Kichenadasse is a medical oncologist and pharmacologist with special interest in the management of variety of cancers including brain, gynaecological, genitourinary (bladder, kidney, prostate), sarcomas, breast, thyroid cancers, cancer of unknown primary and other rare cancers.

Dr Kichenadasse conducts and designs all phases of clinical trials for cancer therapies with a focus on early phase (first-in-human) drug trials.

Clinical trial service providers

Contract research organisations



Avance Clinical

Avance Clinical is the largest premium full-service Australian and USA contract research organisation (CRO) delivering quality clinical trials, with globally accepted data in Australia, New Zealand and the USA for international biotechs. The company's clients are biotechs in their early phases of drug development that need fast, agile and adaptive solution-oriented clinical research services.

Avance Clinical offers pre-clinical services through to Phase 1 and 2 clinical services, leveraging significant Government incentive rebates of up to 43.5% and rapid start-up regulatory processes. With experience across more than 110 indications, the CRO can deliver world-class results and high-quality internationally accepted data for FDA and EMA review.

Avance Clinical uses state-of-the-art technology and gold-standard systems across all functional areas to provide clients with the most effective processes. Medidata, Oracle, IBM Watson and Medrio are just some of their technology partners.

avancecro.com



Syneos Health

Syneos Health® (Nasdaq:SYNH) is a leading fully integrated biopharmaceutical solutions organisation built to accelerate customer success. They translate unique clinical, medical affairs and commercial insights into outcomes to address modern market realities.

Syneos Health bring together a talented team of professionals, who work across more than 110 countries, with a deep understanding of patient and physician behaviors and market dynamics. Together they share insights, use the latest technologies and apply advanced business practices to speed their customers' delivery of important therapies to patients.

Syneos Health supports a diverse, equitable and inclusive culture that cares for colleagues, customers, patients, communities and the environment.

With expertise in drug development in Australia, Syneos Health's Adelaide office provides valuable insight into the pharmaceutical, biotech and medtech landscape as well as the conduct of clinical programs to facilitate the development and commercialisation of new medical and healthcare assets.

syneoshealth.com

Clinical sites



Australian Teletrial Program

Australian Teletrial Program – South Australia (ATP-SA) is expanding clinical trials to rural, regional and remote South Australians. Teletrials provide improved capability to recruit trial participants from rural South Australia and promote diversity, equity and inclusion.

Teletrials improve recruitment into clinical trials, particularly increasing diversity in data collection and including Aboriginal and other vulnerable communities in the trial. The hub and spoke cluster model reduces contract complexity for sponsors.

ATP-SA is building a more interconnected clinical trials system and expanding the reach of clinical trials in South Australia. This increases the potential trial population by 50% (1.2 million > 1.8 million). ATP-SA is increasing the capacity and capability of regional health services to see clinical trials as business as usual. The ATP-SA team can support all aspects of clinical trials including feasibility, study start-up logistics, regulatory processes, clinical trial coordination, protocol development to establish clinical trials and digital/telehealth support.

sahealth.sa.gov.au/saclinicaltrials





CMAX Clinical Research

CMAX Clinical Research has been a leader in delivering early phase clinical trials for 30 years and is one of the most respected clinical trial businesses in Australia.

CMAX Clinical Research has a proven track record of experience and innovation in early phase clinical research and a depth of clinical pharmacology expertise within the team. Their modern clinical trial unit is equipped with 78 inpatient beds and located within Adelaide's BioMed City, providing ready access to state-of-the-art facilities, and world-class medical specialists.

Recent refurbishments include negative air pressure isolation suites and low acoustic zones, allowing optimal flexibility for most study types.

The CMAX teams welcome the challenges of modern complex clinical trial protocols to help their sponsors accelerate their product development. Fusion Clinical Research is a unique service offering which expands CMAX's geographical reach and enables Phases 1-4 clinical trials in primary care settings. Their network provides access to a rich database of patients at a clinical site near to the patient's home.

cmax.com.au

Cancer Research South Australia

Cancer Research South Australia (CRSA) provides compassionate, state-of-the-art cancer care by improving access for patients in South Australia to novel therapies for treatment of cancer.

CRSA conducts phase I, II and III clinical trials and has high-level expertise in all solid tumours, including cancers of the breast, lung, male genito-urinary system (prostate, bladder, kidney and testis), female reproductive system (ovary, uterus and cervix), gastrointestinal tract (oesophagus, stomach and bowel) and melanoma.

Working alongside specialist cancer surgeons, radiation oncologists and all major medical specialties, the team at CRSA ensures each patient's cancer care is optimised, individualised, and of the highest standard.

crsa.au



Southern Oncology Clinical Research Unit

Southern Oncology Clinical Research Unit (SOCRU) is a leading clinical research organisation, located within the Flinders Private Hospital, that specialises in conducting phase I oncology clinical trials. The organisation is staffed by a team of highly skilled and experienced clinical research professionals who are dedicated to advancing cancer research.

SOCRU places a strong emphasis on ethical research practices, patient safety and works closely with regulatory authorities to ensure that all trials meet the highest quality and regulatory standards. SOCRU has extensive experience in conducting trials using a variety of interventions including cytotoxic agents, targeted therapies, immunotherapy and oncolytic viral and cell therapies. By conducting rigorous clinical trials, SOCRU aims to contribute to the development of new cancer treatments that can provide better outcomes for patients and improve the quality of life of people living with cancer.

socru.org.au

Ethics



Bellberry Limited

Bellberry Limited (Bellberry) is an Australian, independent, not-for-profit organisation providing streamlined scientific and ethical review of human research projects, with aims to protect the welfare of research participants and improve the quality, efficiency and effectiveness of research.

Founded 20 years ago, Bellberry initially focused on providing specialist scientific and ethical review for research conducted in the private health sector. Bellberry is now the single largest reviewer of clinical research in Australia, providing Human Research Ethics Committee (HREC) meetings specialist oversight to at least one third of Australia's clinical trial notification (CTN) registered clinical trials annually.

Bellberry holds weekly HREC meetings, and its 125+ HREC members have reviewed over 4,000 studies since its beginnings in 2004. The organisation's research portfolio includes both behavioural and clinical research, and social

sciences projects spanning private, public, academic and government sectors.

Bellberry is at the forefront of global drug development and is the first organisation in Australia to achieve international accreditation for excellence and ethically sound processes in running HRECs by the Association for the Accreditation of Human Research Protection Programs (AAHRPP).

As a not-for-profit, Bellberry redistributes any surplus from its professional review service back into the research sector community to support the advancement of research knowledge through philanthropy and education. Bellberry provides real time expert insight on regulatory

Bellberry provides real time expert insight on regulatory processes including ethics, governance and start-up processes.

bellberry.com.au

Regulated bioanalysis



Agilex Biolabs

Agilex Biolabs, Australia's largest most technologically advanced regulated bioanalytical and toxicology laboratory, provides reliable and defendable bioanalytical, biomarker, and toxicology data, enabling their clients globally to improve human health. They have been recognised for their scale and proven track record for large and small molecule bioanalysis including quality method development, method validation and sample analysis services

Agilex Biolabs' FDA inspected, world-class immunoassay and immunobiology laboratories feature state-of-the-art equipment, including Gyrolab xPlore, MSD Quickplex 120, Luminex Magpix, BD FACSymphony A3 flow cytometer and the droplet digital quantitative real-time analysis for RNA, siRNA, and miRNA clinical trials, which includes vaccines and gene therapy trials. Agilex Biolabs has ISO/IEC17025 accreditation and OECD GLP recognition with NATA to ensure the highest quality standards are met for seamless end-to-end testing for pre-clinical to clinical analysis.

As a global leader in providing flexible solutions, Agilex Biolabs has accelerated numerous biopharmaceutical and pharmaceutical drug development programs from USA, Asia-Pacific and Europe.

agilexbiolabs.com



GNOMIX

GNOMIX provides services to local, national and international scientific communities. Their ethos of client engagement, combined with their unparalleled experience and extensive professional network allows them to provide an effective one-stop shop, providing tailored quality solutions to meet the scale, data content, financial and time constraints specific to your requirements.

GNOMIX is accredited by NATA* to ISO/IEC 17025 standard for laboratory testing.

Their services include:

- · DNA and RNA extraction and Quality Control
- End Point and Real-time PCR
- Digital PCR
- Sanger DNA Sequencing
- Massively Parallel Sequencing (MGI & Illumina)
- Long Read Sequencing (Oxford Nanopore)
- SNP analysis
- · Single Gene and Gene Panels
- Exome and Transcriptome
- Gene Expression
- · Immune Clonality & Repertoire
- Microbiome
- Consultancy

gnomix.com.au

*The National Association of Testing Authorities (NATA) has been Australia's leading accreditation authority for over 70 years. NATA offers world-recognised accreditation for internationally recognised standards across a broad range of industries.

Contract development and manufacturing organisations



BioCina

BioCina is a multi-service biologics contract development and manufacturing organisation (CDMO), focused on the development and cGMP manufacture of microbial-based biological pharmaceuticals, including proteins, plasmid DNA, mRNA, vaccines, cell and gene therapies and biosimilars. End-to-end solutions range from early development through to commercialisation of drug substance.

The BioCina facility, includes fit for purpose spaces for GMP manufacturing, process development, warehouse, manufacturing biological products approved for commercial use by the US-FDA, EMA and Health Canada, including the manufacturing of active pharmaceutical ingredient (API) for use in all stages of clinical trials.

Licensed for GMP manufacture by the Australian Therapeutic Goods Administration (TGA), BioCina is the only GMP manufacturing facility of its kind in Australia that has successfully passed a US-FDA inspection. The team has extensive experience and proven capabilities in microbial process development manufacturing.

biocina.com



Mayne Pharma Services

Mayne Pharma Services is a full-service contract development and manufacturing organisation (CDMO) that offers pharmaceutical development and manufacturing from their GMP & FDA accredited Australian plant.

Mayne Pharma Services partners globally to develop pharmaceutical products from concept to commercialisation quickly and cost-effectively. They offer seamless development which includes manufacture of clinical trial supplies, scale up of new formulations and technology transfer of products through to commercial production.

Mayne Pharma Services has a 40-year history of successfully developing and manufacturing oral and topical products for the global market. Their expertise includes formulation development of modified release capsules, tablets, semi solid and liquids, using best practice assessment techniques and specialised equipment.

From their manufacturing facility in South Australia, Mayne Pharma Services offer a team of highly-skilled scientists to help with the development, validation and optimisation of testing procedures, as well as navigating the complexities of regulatory submissions.

maynepharmaservices.com

Drug storage and distribution



Zuellig Pharma SSG Australia Pty Ltd

Zuellig Pharma is one of the largest healthcare services groups in Asia. Their Australian facility has supported over 1,000 clinical trials, predominately supplying sites in Australia and New Zealand and working with a wide range of research groups.

Services include:

- storage and distribution of clinical trial supplies in a facility that is TGA GMP certified for clinical trial drug storage and secondary packaging
- clinical drug and ancillaries sourcing with global reach and a strong quality management system
- central and local secondary packaging solutions that meet GMP standards.

Additional services include importation, export permits, controlled drugs, SAS and Direct to Patient supply.

The depot is a modern purpose design with validated controlled ambient, cold chain and frozen storage facilities to GMP standards.

zuelligpharma-australia.com.au

R&D, accounting and advisory



RDI Partners (formerly Bentleys R&D Tax Incentives)

RDI Partners, formally Bentleys R&D Incentives, is an award winning, full services corporate advisory firm in Australia.

RDI Partners enable foreign owned and controlled biotech and medtech companies to establish a presence in Australia, conduct research and development (R&D) activities and benefit from the 43.5% R&D Tax Incentive.

The RDI Partners' competitive advantage is underscored by:

- a full-service model, including company establishment and structuring, resident director, accounting and tax, R&D tax, advanced/overseas findings and finance
- depth of technical knowledge in R&D tax, biotechnology and corporate structuring
- track record of seamless service delivery, R&D tax outcomes and overseas finding successes
- strength of relationships with clinical service providers through Australia
- low-cost and low-risk pricing model of a fixed quoted fee where fees are linked to outcomes with no ongoing retainers or monthly charges.



With more than 2,000 researchers and 10,000 staff, Adelaide BioMed City brings together institutes and centres from health and life sciences, clinical care, research, education and industry. The district is home to a range of specialist research institutes and organisations that are supported by a world-class genomics capability, a cancer research biobank and the country's largest public pathology and medical imaging capabilities.

significance through high impact translational research that, when commercialised, drives positive tangible healthcare improvements nationally and internationally.

Combining Australia's most experienced end-to-end clinical trial supply chain with a regulatory framework that provides the fastest pathway to first-in-human (FIH), Adelaide BioMed City enables clinical trial conduct for submission to global regulatory agencies. Adelaide BioMed City incorporates state-of-the-art, FDA-accredited Good Manufacturing Practice (GMP) manufacturing, servicing research and development to commercial scale.

The district is built around the Royal Adelaide Hospital (RAH) and the South Australian Health and Medical Research Institute (SAHMRI), offering a true bedside-to-bench capability with a key focus on research translation to improve health outcomes for patients.

Adelaide BioMed City is home to key health and medical research institutions including:

- · South Australian Health and Medical Research Institute
- · Royal Adelaide Hospital
- The University of Adelaide Health and Medical Sciences
- University of South Australia Cancer Research Institute
- Australian Bragg Centre (due for completion late 2023).

Major hospitals

Royal Adelaide Hospital

The 800-bed Royal Adelaide Hospital is one of Australia's most technologically advanced healthcare facilities and the state's flagship hospital, providing a comprehensive range of the most complex clinical care to an estimated 85,000 inpatients and 400,000 outpatients each year. The state-of-the-art facilities appeal to healthcare professionals, helping to attract some of the best expertise from around the world.

The Royal Adelaide Hospital features:

- leading telehealth facilities that enable staff to consult with colleagues and patients in regional and remote areas across the state and further afield, while digital imaging technology allows clinical images to be streamed live from operating theatres and procedural rooms for diagnostic and training purposes
- the largest automated microbiology system, providing world-class technology to support the timely diagnosis and treatment of infectious diseases
- one of the biggest automated pharmacy distribution systems in the nation, bringing South Australia to the forefront of automated medication technology; and
- the state's only public hospital with a digital instrument tracking system to manage its vast collection of medical equipment.



Supported areas include:

- Oncology
- Cardiology
- Cardiometabolic
- · Orthopaedics and trauma
- · Gastroenterology and inflammatory bowel disease
- Gastrointestinal and pancreatic disease
- Haematology
- · Infectious diseases
- · Immunology and allergy
- Memory
- Neurology movement disorders
- Neurology and neurosurgery
- Nuclear medicine
- Ophthamology
- Adult prevention and recovery care (PARC) - anaesthetic
- · Radiation oncology
- Rhematology



Hospital

The Queen Elizabeth Hospital is a 300+ bed, acute care teaching hospital that provides inpatient, outpatient, emergency and mental health services for more than 250,000 people living primarily in Adelaide's western suburbs.

Clinical trials

The Queen Elizabeth Hospital Cancer Clinical Trial Unit specialises in the conduct of first-in-human studies to Phase IV across a broad range of haematology and oncology indications and has participated in more than 400 studies.

The Basil Hetzel Institute for Translational Health Research

The purpose-built Basil Hetzel Institute for Translational Health Research is the productive research arm of The Queen Elizabeth Hospital. It is located opposite the main campus of The Queen Elizabeth Hospital, just 8 minutes from the Royal Adelaide Hospital.

Research themes include ageing, cancer, cardiovascular disease, chronic disease, clinical sciences, health services

All research groups have strong links to clinical divisions within The Queen Elizabeth Hospital underpinning translational health research. The 'bench-to-bedside' approach is at the forefront of an emerging area of medical science that aims to improve public health through collaborative discoveries and innovations in patient care, education and research.

The Basil Hetzel Institute for Translational Health Research has long-standing teaching and research affiliations with The University of Adelaide, the University of South Australia and Flinders University, which offer a range of undergraduate and postgraduate research training opportunities.

Supported areas include:

- Oncology
- Cardiometabolic
- Intensive care
- Inflammatory bowel disease
- Memory
- Surgery

Flinders Medical Centre

Part of the Southern Adelaide Local Health Network (SALHN), Flinders Medical Centre (FMC) is the largest hospital in the southern metropolitan area of Adelaide, with more than 5,000 skilled staff providing an extensive range of services for patients of all ages. The hospital is co-located with the Flinders University School of Medicine and Flinders Private Hospital.

FMC has earned an international reputation as one of Australia's finest public teaching hospitals and a centre for research excellence. SALHN provides care for approximately 350,000 people living in the southern metropolitan area of Adelaide as well as providing a number of statewide and regional services.

Clinical trials

The Department of Medical Oncology at FMC provides a comprehensive specialist service for patients with cancer. The Oncology Team at FMC treat patients diagnosed with any solid-tumour cancers, using their team of Allied Health professionals to support patients and carers with physical and psychological needs.

The Department of Medical Oncology is involved in a number of clinical trials investigating new or potentially improved cancer treatments. Treatment trials for most common cancers including breast, prostate, metastatic melanoma, pancreas, lung, colon and gastricoesophageal cancer are in progress.

Lyell McEwin Hospital

The Lyell McEwin Hospital is a major tertiary hospital north of Adelaide and part of the Northern Adelaide Local Health Network (NALHN), which delivers services to more than 400,000 people living in Adelaide's north and north-eastern suburbs and regional areas. The northern area of Adelaide is currently the highest population growth area in South Australia, and by 2026 is expected that a quarter of the state's population will live in the northern metropolitan catchment area.

The Government of South Australia has allocated over AUD\$57 million for expansion of the hospital to double the capacity of the emergency department. This project is currently underway.

Clinical trials

The Northern Adelaide Local Health Network has dedicated clinical trial managers and facilities for sponsored clinical trials. The Clinical Trial Unit conducts trials and has a dedicated research team for the following indications:

- Endocrinology
- Gastroenterology and Hepatology
- Psychiatry
- Cardiology
- Gastroenterology
- Renal
- Respiratory

Trial staff are Good Clinical Practice (GCP) certified and highly experienced in the use of electronic data capture, electronic capture Patient Reported Outcomes (PROs), conducting ECGs, venepuncture, processing and shipping laboratory samples.

Women's and Children's Hospital

The Women's and Children's Hospital is South Australia's largest specialist facility for women's and children's health. It is South Australia's leading provider of care for children with acute and chronic conditions in South Australia and the state's largest maternity and obstetric service.

Highly regarded as a centre for research, the Women's and Children's Hospital works with all three South Australian universities in the training of hundreds of health professionals each year. The Women's and Children's Hospital aims to be a leader in quality health research, partnering with other agencies, and translating research into innovative and improved services.

Clinical trials

The Vaccinology and Immunology Research Trials Unit (VIRTU) is part of the Women's and Children's Hospital and affiliated with the University of Adelaide. VIRTU's vision is to optimise protection against vaccine preventable disease to reduce death and disability in children. VIRTU conducts trials to develop safe and effective vaccines that can be introduced into the community to prevent many childhood diseases, leading to improvement in children's overall health and wellbeing.

VIRTU is recognised nationally and internationally for conducting clinical trials to an excellent standard and has been involved in immunisation research since 1997. The multidisciplinary group is comprised of doctors, nurses, scientists and research staff. Clinical trials carried out within the unit include licensed vaccines, new vaccines and combination vaccines.

^{1.} Northern Adelaide Local Health Network 2018-19 Annual Report (presented September 2019), Northern Adelaide Health Network



The SAHMRI Registry Centre, established in 2018, provides an important and rich source of translational and observational research data. It brings together a collaboration of registries including those based within SAHMRI, as well as member registries based externally.

Clinical trials

SAHMRI has a well-established reputation in the conduct and independent oversight of local, national, and international phase I to IV clinical trials covering a diverse range of diverse therapeutic areas including cardiology, oncology, nutrition, metabolic disorders, immunology, paediatrics, pregnancy, medical devices as well as healthy volunteers.

SAHMRI has significant clinical trial expertise and provides a central resource for conducting and coordinating clinical trials. SAHMRI's Clinical Trials Platform together with the Biostatistics Unit, provide professional services and support for researchers and industry sponsors who need assistance at any stage of the clinical trials life cycle, including grant development, statistical support and all aspects of clinical trial design and conduct. Their vision is to accelerate the translation of research into real-world impact by providing exceptional, participant-centred clinical trial services and support.

The Clinical Trials Platform aims to provide:

- easier, more equitable access to trial involvement for patients and the public
- innovative ways of designing and conducting clinical trials that prevent disease or deliver treatments faster by using new and emerging technologies
- support for researchers and industry sponsors who need assistance at any stage of the clinical trials life cycle which includes grant development, statistical support and all aspects of clinical trial design and conduct
- support for rapid and efficient study start-up including assistance with ethics submissions, contract development and negotiation
- high quality systems and processes that underpin clinical trials conduct to ensure we align to best practice examples.

Molecular Imaging and Therapy Research Unit

Located within SAHMRI, the Molecular Imaging and Therapy Research Unit (MITRU) is home to South Australia's only cyclotron, a particle accelerator that produces radioactive isotopes for use in medical imaging, treatment and research. MITRU is licensed by the Therapeutic Goods Administration (TGA) as a manufacturer of radiopharmaceuticals which are supplied daily to hospitals and imaging centres all over Australia.

MITRU is increasingly supplying radiopharmaceuticals for research purposes including clinical trials.

MITRU specialises in positron emission tomography (PET) imaging tracers. These tracers bind to target cells in the body and emit radiation which is detected by a PET scanner at the imaging facility. The scanner then combines the reading with a CT scan of the patient to show where in the body the target cells are located.

A specialist manufacturer of Lutetium-177 [177Lu] based therapies, once administered, these therapy agents bind to the target cell (typically cancerous cells) and emit radiation. The radiation destroys the cell that it is bound to without irradiating surrounding tissues. MITRU supplies [177Lu]PSMA-617 to imaging centres registered for particular clinical trials.

In a world-first for cancer scan innovation, MITRU was the first to be granted a TGA licence to manufacture the fluorinated prostate specific membrane antigen for clinical use in 2019.

In collaboration with universities, institutions and private companies, MITRU is actively involved in researching new radiopharmaceuticals which target different cells in the body in order to image or treat new conditions.

Australian Bragg Centre for Proton Therapy and Research

Located within Adelaide BioMed City and set alongside the South Australian Health and Medical Research Institute (SAHMRI), the Australian Bragg Centre for Proton Therapy and Research is a purpose-built biomedical development that will be home to leading cancer research institutes as well as the first clinically dedicated proton beam precision therapy centre in the Southern Hemisphere. Housing an additional 500 researchers, including key opinion leaders, over 14 levels, the building is due for completion in late 2023.

The Centre will provide advanced precision proton radiation, delivering precise, non-invasive radiotherapy that can destroy cancer cells, while minimising the damage to surrounding healthy tissue and vital organs. This enables treatment with less side effects for paediatric, adolescent and young adult patients and those with rare cancers.

The South Australian Paediatric Brain Cancer Biobank, led by internationally renowned brain cancer specialist Professor Jordan Hansford, will be able to support critical research into this advanced mode of therapy, with hundreds of additional paediatric patients expected to be referred to Adelaide for treatment from around Australia.

The Centre will be an integral part of global network undertaking proton therapy research. As a relatively new treatment option, and one that remains expensive and not widely available, proton therapy has only been validated against a small range of cancers. The technology is potentially beneficial in treating many other diseases, but more research is needed in these areas to prove its efficacy.

PARC Clinical Research (University of Adelaide)

Led by Professor Guy Ludbrook, PARC Clinical Research is a University of Adelaide-based research group conducting specialised research into multiple disciplines. The purpose of PARC is to undertake contract clinical research for the pharmaceutical and biotech industries and to provide a safe and suitable environment for the conduct of academic clinical studies. PARC has extensive experience in the conduct of clinical research with compounds of narrow therapeutic index, including opioids and products in early phase of development that require specialised management, as well as a large amount of experience in the conduct of studies in a broad range of therapeutic areas and across various development stages.

Located in the Royal Adelaide Hospital, PARC has access to a large number of specialist clinicians, many who require a unique and flexible facility such as PARC to conduct their clinical research studies, or who can provide patient referrals.

PARC's highly specialised clinical facility allows for intensive monitoring for narrow therapeutic margin (higher risk) therapies and their non-hospital allocated beds allow for overnight and participant studies to be conducted with ease. Their highly trained and skilled staff have expertise in trial conduct across most formulations, with special expertise in the dosing and handling of schedule 8 and intravenous and infusion therapies.

The technology

The Australian Bragg Centre for Proton Therapy and Research will operate a Radiance 330 proton beam therapy system.

The Radiance 330 system is based on a proton synchrotron accelerator and is designed to deliver superior dose sculpting and higher beam efficiencies compared with other methods of proton beam delivery. It has the highest beam energy available on the market with unique capabilities in performing proton radiography and computed tomography².

The design of the Australian Bragg Centre for Proton Therapy and Research has been developed and reviewed by a team of local and international experts including experienced clinicians, suppliers and consumer advocates. It will consist of three radiotherapy treatment rooms. Two treatment rooms will include 180-degree rotating gantries and the third room will house two fixed, horizontal beamlines.

² The technology, Australian Bragg Centre for Proton Therapy and Research https://www.protontherapy.sahmri.org.au/about/the-technology/



Health Data and Clinical Trials (HDCT) brings together more than 70 years of clinical trials and health data expertise to support researchers and enhance research outcomes. The team comprises multi-disciplinary specialists available to help researchers refine proposals, collaborate, upscale, budget, design and deliver unique clinical trials and health data science. They are experts in the delivery of unique clinical trials and health data science, ranging from registries and translational work to Phase I to Phase IV randomised controlled trials across a broad range of therapeutic areas – for both industry and acadaemia.



South Australian immunoGENomics Cancer Institute

The South Australian immunoGENomics Cancer Institute (SAiGENCI) is an independent cancer-focused medical research institute focusing on cancer research and clinical trials, which includes new cutting-edge technologies in immunotherapies and genomics.

SAiGENCI is the state's world-class cancer research institute, jointly resourced by the Federal Department of Health, Central Adelaide Local Health Network and the University of Adelaide. The Institute will collaborate externally, with like-minded centres of excellence across the globe, delivering world-class and life-changing treatments and outcomes for cancer patients.

SAiGENCI's objectives include:

- forging strong research collaborations
- developing and testing new technologies and discoveries
- improving treatment and care options for people living with cancer
- training South Australian clinicians
- · commercialising new discoveries.

Key research areas include:

- · drug discovery and development
- tumour inflammation and immunotherapy
- computational systems oncology
- epigenetics
- single cell and spatial technologies.



Robinson Research Institute

The Robinson Research Institute at the University of Adelaide is a collective of internationally leading researchers who work across four key themes:

- · fertility and conception
- · pregnancy and birth
- · early origins of health
- child and adolescent health

Their 45+ research teams are uncovering how events and circumstances before birth and during early life impact an individual's healthy development, their susceptibility to disease and their resistance to adversity. These discoveries are being used to develop effective interventions to protect children and improve their health prospects throughout life.

Their research is novel as it includes the critical period prior to conception. As the preconception period is critical for a healthy pregnancy and establishing the health trajectory of the developing fetus, they also consider the health, environment and social circumstances of prospective parents.

Robinson Research Institute's 400+ members manage research projects, clinical trials and cohort studies, and collaborate across many disciplines including biomedical, clinical, social, and epidemiological science to generate new discoveries that will improve reproductive health in parents and tackle life-long health in children.

Digital Health Cooperative Research Centre

The Digital Health Cooperative Research Centre (DHCRC) connects industry, government, providers, consumers, academia and research to solve the most pressing healthcare challenges. In collaboration with over 56 participant organisations, the DHCRC invests in research and development to support the growth of a strong digital health industry, improve patient outcomes and experience and deliver sustainable digital health solutions.

Innovation districts

Our sectors co-exist in hi-tech hubs and research centres, forging collaborative ecosystems that open doors and inspire new ways of thinking.

Defence Super District

34kms from CBD

Key national defence research, manufacturing and sustainment hub housing the RAAF Base Edinburgh, Defence Science and Technology Group and major defence companies.

Osborne Naval Precinct

26kms from CBD

Australia's largest naval shipbuilding hub incorporating a critical mass of world-class warship design and construction skills. Significant upgrades are slated to make it the most technologically advanced naval shipyard in the world.

Technology Park

17kms from CBD

Hub for systems development and integration, information communications technology, advanced manufacturing and electronics, and home to over 100 small to medium enterprises, multinationals and start-ups.

Adelaide BioMed City

Adelaide CBD

AUD\$3.8 billion and medical innovation district with leading edge anchor institutes and companies that cluster and connect with startups, business incubators and accelerators.

Lot Fourteen Innovation District

Adelaide CBD

Australia's first ideas and innovation neighbourhood and home to the Australian Space Agency, SmartSat CRC, Defence and Space Landing Pad, FIXE start-up hub, MIT Adelaide Living Lab, Australian Institute for Machine Learning and the Australian Cyber Collaboration Centre.

Tonsley Innovation District

12kms from CBD

Home to high-value manufacturing industries including defence, health, medical devices and assistive technologies, clean tech and renewable energy, software and simulation, mining and energy services.

Adelaide CBD



Lot Fourteen Innovation District

Australia's premier hi-tech innovation precinct.

Location: Adelaide CBD

Focus: Space, defence and critical technologies. Lot Fourteen connects universities, researchers, entrepreneurs, start-ups and companies, such as:

- Digital Health Cooperative Research Centre
- · MIT Adelaide Living Lab

- · The University of Adelaide
- · Australian Institute for Machine Learning
- · Australian Cyber Collaboration Centre
- · Australian Space Agency
- · Defence and Space Landing Pad
- FIXE start-up hub

Commercial tenants include Microsoft Azure, Commonwealth Bank, Amazon Web Services Applied Sciences and Salesforce.

Tonsley Innovation District

Global benchmark for reimagining and redeveloping traditional manufacturing facilities.

Location: 10kms south of the Adelaide CBD

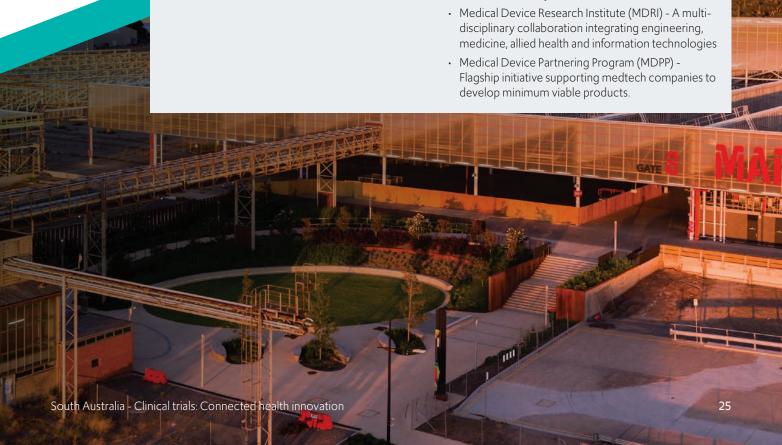
Focus: High-value manufacturing and innovation, connecting leading-edge research and education institutions, established businesses, start-ups, incubators and accelerators, government and the community.

Focus sectors:

- · Medtech and medical devices
- Industry 4.0, automation and software
- Cleantech
- Energy

Capabilities include:

- · Global Centre for Modern Ageing
- · Flinders Digital Health Research Centre
- · Micro-X
- Aged Care Research and Industry Innovation Australia (ARIIA)
- Zeiss
- · Line Zero Factory of the Future
- BAE Systems
- · Siemens Energy
- · Hydrogen Park SA
- Flinders Village: a biomedical precinct with innovation hub and Medical Device Research Institute (MDRI) connected to nearby Flinders University. Flinders Village brings an advanced biomedical research centre together with an academic and hospital cluster that includes Flinders Medical Centre, Flinders Private Hospital, and Flinders University





Adelaide is Australia's home for artificial intelligence (AI) and data analytics driven innovation, and is leading the nation in AI in healthcare.

The Australian Institute for Machine Learning (AIML), ranked in the top six globally for computer vision (csrankings.com), is Australia's largest Al capability. The Massachusetts Institute of Technology's (MIT's) Adelaide Living Lab links South Australia through to MIT's world-leading data analytics capabilities. Together they are the foundation of the state's knowledge ecosystem, generating new knowledge and technologies.

The Australian Research Centre for Immersive and Virtual Environments (IVE) completed more augmented reality research than any other institution or university globally and adds world-leading capabilities in narrative visualisation and human centred design to our innovation ecosystem.

The Australian Cyber Collaboration Centre is also based in Adelaide and is a central connection point for organisations looking to improve their cyber resilience and data protection capabilities.

South Australia's position as a global leader in AI has attracted some of the world's most innovative and forward-thinking organisations. Amazon Web Services, Microsoft Azure, Nokia, Accenture, Deloitte, PwC, MTX Group and Telstra Health (Dr Foster) have established operations in South Australia, focused on delivering AI innovation

South Australia's robust healthcare and data management systems are uniquely positioned for developing, applying and commercialising AI solutions for global health problems.

South Australia is embracing the ability for AI to deliver the biggest transformative impact to healthcare in decades. Government, industry and academia work together to transform health system efficiency, driving better operational and clinical decision-making and improving patient outcomes.

World-leading Al research capabilities

- · Australian Institute for Machine Learning
- Centre for Augmented Reasoning
- MIT Adelaide Living Lab
- · Digital Health CRC
- Research Centre for Immersive and Virtual Environments
- Amazon Web Services Applied Sciences

Australian Institute for Machine Learning

The Australian Institute for Machine Learning (AIML) is a key anchor tenant of Lot Fourteen, Australia's leading hi-tech innovation precinct. AIML works with leading global pharma and digital companies including Roche, GSK and Medtronic, pushing the frontier of precision health.

AIML is a member of the global Alliance of Centers of Artificial Intelligence in Medicine, which includes Stanford University, Harvard University, and the Mayo Clinic.

AIML ranks in the top six worldwide in computer vision (csrankings. com) and is the top site in Australasia for artificial intelligence research generally, with world-class expertise in the methods that support this, artificial intelligence, computer vision, and deep learning. Their key research themes also include robotic vision, natural language processing and visual question answering, medical machine learning, space, defence and agriculture.

The institute is led by Professor Simon Lucey, who spent 10 years with Carnegie Mellon University's Robotics Institute.

Collaboration with the South Australian Health and Medical Research Institute

The South Australian Health and Medical Research Institute (SAHMRI) offers significant clinical trial expertise and provides a central resource for conducting and coordinating clinical trials. SAHMRI's ability to collect, manage and store real life, large data sets coupled with the ability to apply artificial intelligence, including machine learning for insight and prediction through collaboration with AIML, are central to SAHMRI's reputation as an internationally recognised leader in clinical trial coordination and completion.



Centre for Augmented Reasoning

AIML's Centre for Augmented Reasoning leads the research and development of new augmented systems and improves machine learning technology across a range of applications, for example:

- machines that continually learn new things while interacting with the environment
- machines that work with data analysts to optimise business processes
- machines that can ask people questions in ways that are more natural and easier than filling in forms
- robots that can understand and follow instructions from people; and
- factories where people and machines work seamlessly together without the need for constant reprogramming of software.

AIML's major research themes:

- deep learning
- · computer vision and robotic vision
- natural language processing and visual question answering
- · medical machine learning
- space
- · defence; and
- · agriculture.

AIML is globally recognised as:

- largest Machine Learning Group in Australia 160+ people, and growing
- top six in the world in publications in the key conferences in computer vision (csrankings.com)
- first PASCAL Visual Object Classes repeatedly
- first NIH MEDICAL VQA CHALLENGE 2020 (IMAGECLEF)
- first REFUGE Retinal Fundus Glaucoma Challenge 2019
- first Nuclei Segmentation Challenge 2019
- first European Space Agency Pose Estimation Challenge 2019
- second Oz Minerals Explorer Challenge 2019
- first Volkswagen Logistics Innovation Day in Shanghai, 2019
- first Facebook Visual Question Answering 2.0 challenge
- · first CityScapes in 2018; and
- · second ImageNet Scene Parsing 2016.

Australian Institute for Machine Learning – Medical

AIML has established clinical research-focused partnerships with both state-funded and commercial organisations.

Global pharma, biotech and technology partners:

- Roche
- GlaxoSmithKline
- Siemens Healthineers
- MIT Adelaide Living Lab
- · Amazon Web Services; and
- LBT Innovations.

AIML's local clinical research partners:

- · SA Health
- · South Australian Health and Medical Research Institute
- Royal Adelaide Hospital
- · Women's and Children's Hospital
- SA Pathology
- SA Pharmacy
- SA Medical Imaging; and
- BreastScreen SA.

AIML clinical areas of focus:

- · clinical trials/drug development/testing
- · treatment response leukemia
- proteomics, lipidomics, metabolomics
- lipidomics to predict cardiovascular disease and treatment response
- · breath analysis
- genomics/Statewide Genomics Centre
- · immunotherapy response imaging
- cardiovascular imaging
- gastrointestinal colonoscopy
- colorectal cancer
- chest computed tomography/X-ray
- orthopaedics
- ophthalmology
- · critical care; and
- · breast cancer.

Australian Research Centre for Interactive and Virtual Environments

Leading edge immersive capability, the Australian Research Centre for Interactive and Virtual Environments (IVE), is a world leader in Augmented Reality (AR) and Virtual Reality (VR) and has produced the most AR papers of any institute or university in the world.

Led by Professor Bruce Thomas as Director, IVE brings together a team of world-leading researchers in AR and VR. Professor Thomas is nationally and internationally recognised for his contribution to wearable computers, laptop interactions, Augmented Reality and user interaction. Also forming a part of the IVE leadership team is Deputy Director Professor Mark Billinghurst. Professor Billinghurst is recognised for his expertise in AR, exploring innovative computer interfaces that merge virtual and real worlds. He has received several accolades for his contribution to human interface technology research.

IVE is a unique alignment of computer science, engineering, art, architecture and design. IVE is responding to the challenge of increased demand for AR and VR technologies globally, with leading research in many areas of AR and VR including wearable computing, interface design, empathic computing, 3D visualisation, perception and telepresence.

IVE is leading the next wave of AR and VR technologies.

With internationally recognised visual effects capabilities and leading research in virtual and augmented realities, South Australia is leading the way as an Australian destination for companies to partner, innovate and transform.



Let's talk

Connect with our Health team.

China

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