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Melbourne Children's Trial Centre



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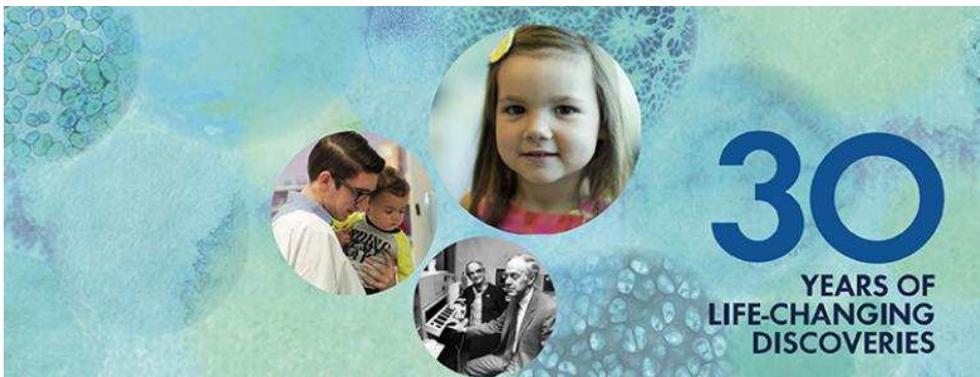
The Royal Children's Hospital (RCH)

<http://www.rch.org.au/home/>



Murdoch Childrens Research Institute (MCRI)

<https://www.mcri.edu.au/>



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<http://www.melbournechildrens.com/mctc/>

MCTC is a unique collaboration between the Royal Children's Hospital (RCH), The Murdoch Childrens Research Institute (MCRI), The Royal Children's Hospital Foundation and The University of Melbourne (UoM). These Institutes bring together expertise in research, clinical practice and education.

Associate Professor Andrew Davidson is the Medical Director of MCTC, also a Senior Staff Anaesthetist at RCH and Head of Anaesthesia Research, MCRI. As

Medical Director, Prof Davidson works to facilitate research for clinical research staff at RCH and the MCRI, supported by a team of dynamic, innovative and multidisciplinary professionals who have extensive and unique experience in the field of clinical trials.

MCTC's vision is to lead Australia in the design and conduct of paediatric clinical trials with foundations in quality, efficiency and innovation. The aim of MCTC is to enable researchers to bring new and novel therapies to children earlier, and generate knowledge to improve healthcare for children. The centre is run by a team of staff who have collaborated on numerous clinical drug trials, which range from phase I to phase IV studies, single centre and international multicentre trials, and include pharmacokinetic, bioequivalence and pharmacodynamics studies.



Conducting paediatric clinical drug trials with Melbourne Children's Trial Centre

MCTC includes a dedicated clinical trials unit directed by Associate Professor Noel Cranswick, a paediatric clinical pharmacologist. Established in 1998, this facility conducts high quality clinical trials in children. The unit is run by a dynamic, multidiscipline team of professionals who have extensive clinical trials experience.

MCTC staff have collaborated on numerous clinical drug trials. These range from phase I to phase IV studies, single centre and international multicentre trials, and include pharmacokinetic, bioequivalence and pharmacodynamics studies.

MCTC is experienced in all aspects of clinical drug trials, including protocol development, case report form design, ethics committee submissions, subject recruitment, study coordination, study evaluation and financial management. All aspects of clinical trial management are carried out in accordance with the Therapeutic Goods Administration

Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Declaration of Helsinki, and the National Health and Medical Research Council National Statement on Ethical Conduct in Research Involving Humans.



MCTC conducts clinical drug trials, which encourage the quality use of medicines in children. The unit pursues new analysis techniques and fosters expertise in drug evaluation and pharmacoeconomics. It sets out to monitor and develop new therapeutic regimens, trains specialist laboratory and clinical staff and teach medicine and clinical pharmacology to undergraduates and postgraduates. MCTC strives to provide a quality clinical and laboratory service to the public in paediatric clinical pharmacology, toxicology and therapeutics.

Our facilities for inpatient and outpatient clinical trials are child and family friendly and provide a non-threatening environment. The pain and discomfort of any procedures and minimised by therapies such as local anaesthetic

creams, and supportive strategies like distraction, music therapy and play therapy are used.

Standard Operating Procedures

MCTC staff operate according to established standard operating procedures (SOPs). SOPs ensure that all data obtained is collected and recorded with accuracy, consistency and integrity and trials are conducted in accordance with ICH/GCP guidelines.



Royal Children's Hospital Human Research Ethics Committee (HREC)

The Royal Children's Hospital Human Research Ethics Committee meets monthly, applications are required to be submitted approximately five weeks prior. If there are no queries with a research protocol, approval is usually granted within one week of the meeting.

The HREC provides an advisory service to assist investigators and study coordinators with patient/parent information statements and consent forms prior to submission. The committee is also required to monitor all research projects they have approved, requiring the researchers to produce progress

and final reports.

The members of the committee are familiar with the requirements of early phase studies in children and approve several such studies each year.

Clinical Trial Recruitment

MCTC acknowledges the importance of focused recruitment and ensure recruitment targets are met by:

- assessing the feasibility of proposed studies
- designing, implementing and evaluating detailed recruitment strategies
- screening prospective study subjects and their families

Feasibility studies provide essential information on estimated recruitment targets. Obstacles and/or challenges that may impact on the success of the trial and how they may be overcome can also be identified at this stage. The comprehensive patient screening process adopted ensures optimal enrolment of patients within a defined period, whilst nurturing patient retention.

MCTC has established links with general paediatrics, community and ambulatory medicine, thoracic medicine, gastroenterology, neurology, neonatal medicine, endocrinology, cardiology, rheumatology, haematology/oncology, dermatology, immunology, infectious disease, adolescent medicine, surgery and anaesthetics, enabling trials to be performed in many areas of clinical practice.

MCTC is also committed to developing relations with local community groups and health professionals. These links include; general practitioners, paediatricians, maternal and child health nurses, day-care centres, schools and local, metropolitan and state newspapers and medical publications.

Clinical Trial Coordinators are pivotal members of the clinical trial team

MCTC clinical trial coordinators have extensive knowledge in all aspects of clinical drug trials in children and are experienced senior paediatric nurses. MCTC coordinators are a highly motivated core group of professionals who are aware of the challenges faced by paediatric clinical trials and are experienced in recognising and overcoming these issues.

The strong communication skills combined with the extensive clinical and research experience of MCTC clinical trial coordinators ensures all clinical drug trials are conducted in a professional manner in accordance with international and local regulations.



Advocacy

The Royal Children's Hospital is an important advocate to government, industry and the community on behalf of children. Specifically, MCTC advocates for the quality use of medicines in children.

Regulation

MCTC staff have expertise in drug regulatory issues. Advice is given on matters relating to the preparation of submissions for government evaluation, both in Australia and internationally. MCTC offers independent advice on regulatory matters from early phase trial design through to post marketing procedures. An audit service has also been developed for organisations that may require this.

Drug informatics

MCTC regularly provides advice on toxicity and use of drugs in children to clinicians, nurses and paramedical groups.

Toxicology

MCTC in association with the Royal Children's Hospital Emergency Department, Intensive Care Unit and the Poison's Information Centre is developing a toxicology service. A toxicology database has been developed as a surveillance and research tool.

Complementary and Alternative Medicine (CAM)

The use of complementary and alternative medicine (CAM) is becoming increasingly popular within the Australian community. There exists, however, a potential for adverse events and children may be at a particular risk. In association with the Royal Children's Hospital Department of General Medicine, MCTC is involved in a surveillance study of CAM associated adverse events in children. The surveillance of adverse events is conducted via the resources of the Australian Paediatric Surveillance Unit (APSU). This system allows monthly reporting of adverse events by paediatricians.

Traditional Pharmacokinetics

MCTC has expertise in traditional pharmacokinetic methods. The staff have analysed traditional pharmacokinetic studies including bioavailability studies which have been accepted by the TGA as part of new drug applications.

Population Pharmacokinetics

Within the department there are several ongoing pharmacokinetic studies using population methods. The unit is currently an academic centre of excellence for Pharsight software manufacturers, having been recognised for our expertise in using their products for pharmacokinetic analysis.

Trial Design

MCTC is experienced in several alternative trial designs, with a particular interest in novel paediatric placebo controlled trials and single patient (n=1) studies. Advice on appropriate ethical protocol design is also available.

Pharmacogenomics

Pharmacogenomics is a developing field in which the genes that are important in drug metabolism are studied. Tests are developed to predict how drugs are handled in the body, and which individuals are at risk of side effects. MCTC collaborates with other organisations to offer a comprehensive approach to this exciting field.

Genotyping has become part of all stages of drug trials and our pharmacogenomics unit is ready to incorporate such genetic studies into new drug trials. Pharmacogenomics brings together staff with expertise in pharmacology, pharmacy, molecular genetics, statistical genetics and epidemiology.

Pharmacoeconomics

MCTC is developing expertise in pharmacoeconomics. We offer a specific consultative service into the pharmacoeconomic analysis of paediatric data in a clinical setting.



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