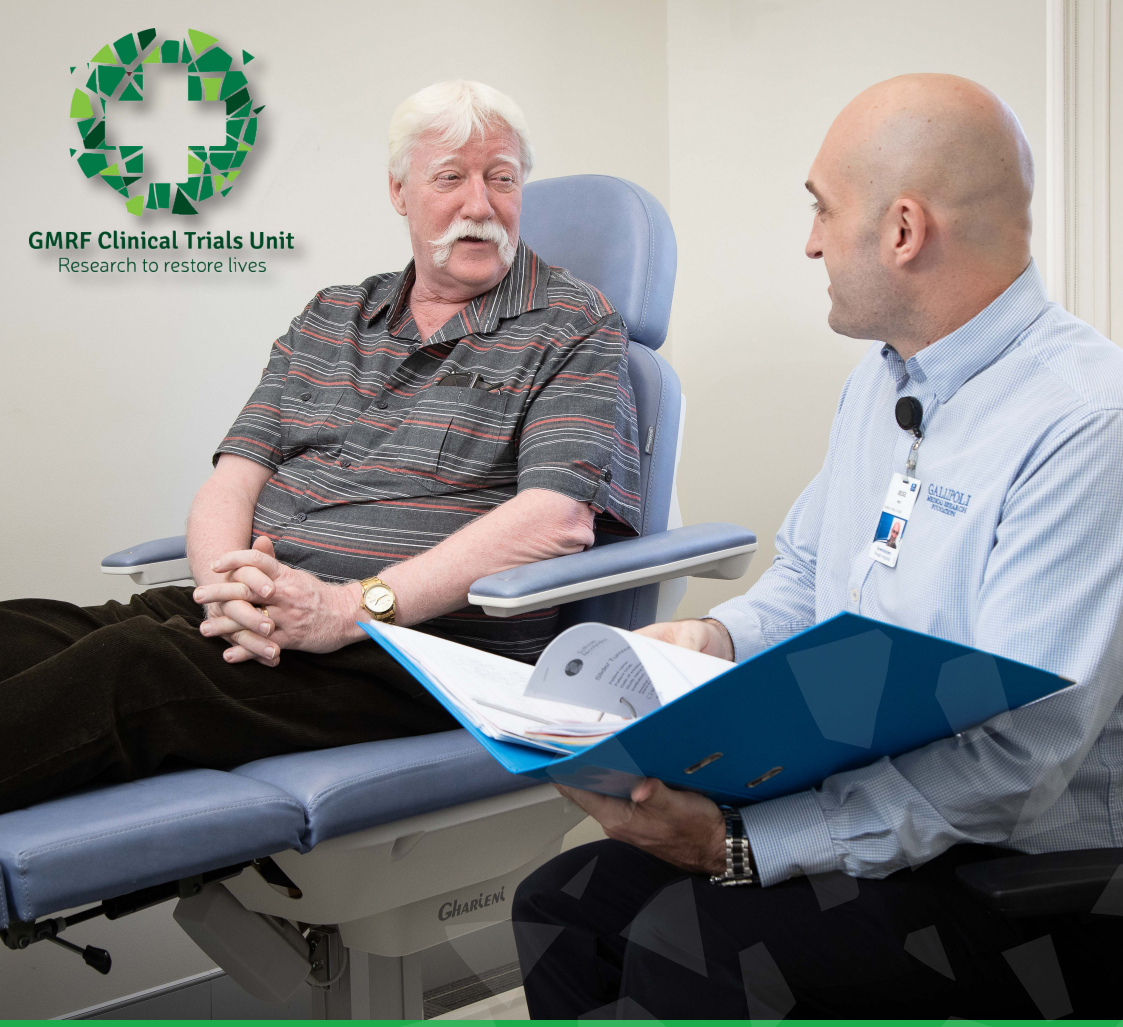



# Research to restore lives

Gallipoli Medical Research Foundation

## Clinical Trials Unit

Greenslopes Private Hospital
Part of Ramsay Health Care

GALLIPOLI
MEDICAL RESEARCH FOUNDATION
Remembrance through research

# Facilitating advances in medical treatment

**Gallipoli Medical Research Foundation is an Approved Research Institute (ARI) committed to enhancing the health of the Australian community through the highest quality medical research.**

**Our dedicated Clinical Trials Unit delivers high quality results for studies of emerging new medications and better tolerated therapies for the benefit of our participants and the wider community.**

The Clinical Trials Unit of the Gallipoli Medical Research Foundation (GMRF) is proud to be based within the campus of Greenslopes Private Hospital (GPH), the largest private teaching hospital in Australia.

In addition to the benefits of the strong history of research in the hospital, our location provides us with access to a large population of Consultants and Visiting Medical Officers based at GPH.

## Leading through specialisation

### Therapeutic areas

GMRF has the expertise and facilities to conduct trials in a wide range of therapeutic areas. The unit also collaborates with a variety of highly engaged investigators and has access to the knowledge of academic research streams within GMRF.

Our Clinical Trials Unit has extensive experience in the following indications:

**Liver disease**

**Oncology & Haematology**

**Including metastatic melanoma, prostate, lung and gastric cancers**

**Respiratory disease**

In 2014 and 2017, the GMRF Clinical Trials Unit was awarded 'Best/Favourite Site' by ARCS Australia. The unit was nominated by industry colleagues in recognition of it's: **"Excellent facilities with highly trained, dedicated staff and proactive support of sponsor activities".**

# Our Strength is Our People

**“This is the best team I have ever worked with in my many years of doing trials!”**

Prof Darrell Crawford (GMRF Director of Research, Principal Investigator in Hepatology and Head of the School of Clinical Medicine, University of Queensland).

## Staff

**The GMRF Clinical Trials Unit is purpose built with a team of dedicated professionals.** With a combined experience of over 150 years in a broad range of therapeutic areas, the Clinical Trials Unit emphasises the importance of teamwork in providing the highest quality trial conduct.

The day to day oversight of the unit is managed by the Clinical Trials Manager, who has over 25 years of experience working in drug development.

The Unit is composed of six experienced Clinical Trial Coordinators, three Data Manager/Entry Officers (including one with unit training responsibilities), two Ethics Coordinator/Assistant, two Clinical Trials Assistants and a Clinical Trial Administrator. Our highly responsive staff work together to deliver on contract obligations. We have staff proficient in performing:

- ECGs & vital sign measurement
- Blood collection and processing (including IATA Dangerous Goods Shipper certification)
- Respiratory assessments

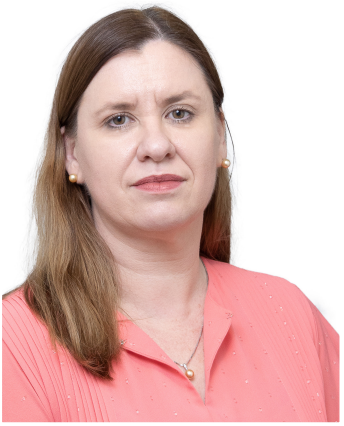
The team use a range of electronic Case Report Forms such as InForm, Medidata Rave and many others. We focus on rigorous and continuous training of CTU staff. All staff members (including Investigators) undergo training in ICH-GCP every two years.

## Investigators

Many of the GMRF Clinical Trials Unit's Investigators are key opinion leaders in their fields. These clinical specialists are also trained in ICH-GCP and work in partnership with the GMRF team to ensure protocol compliance, participant safety and accurate data collection.

**"My patients really benefit from the support they receive from the team at GMRF".**

Dr Victoria Atkinson
(Principal Investigator, Oncology)



# Our Advantage

## Collaborators

The Clinical Trials Unit has strong working relationships with the GPH community. Staff work closely the Cyril Gilbert Cancer Centre on oncology and haematology studies, and with heptologists and respiratory physicians for related studies. A Memorandum of Understanding is in place with the third party service providers supporting clinical trials, including:

- Ramsay Healthcare Pharmacy
  - Dedicated clinical trials pharmacist on staff and onsite facilities.
- Sullivan Nicolaides Pathology
  - Local and central laboratory facilities for full pathology support.
- Queensland X-Ray
  - Full radiology services and RECIST reporting
- GPH Lung Function Unit
- Other service providers as required, for example; cardiology, dermatology and ophthalmology.

## Equipment and Facilities

GMRF offers the following facilities and equipment:

- Dedicated clinical trials laboratory
- Temperature monitored fridges, -20°C and -80°C freezers
- Refrigerated centrifuge
- ECG machine
- Vital signs machine
- Spirometer
- Fibroscan machine
- Dedicated consultation rooms
- Trial monitor facilities
- Secure facilities for participant medical record storage
- Offsite secure archiving

## Study feasibility and Start-Up

To optimise the study start up process, contract preparations happen in parallel with ethics approval.

The feasibility of any potential study is thoroughly assessed to ensure the protocol is clinically relevant and that there are sufficient on-site resources and the required patient population available to meet recruitment targets.

GMRF uses the Greenslopes Research and Ethics Committee (GREC) for trial submissions. The Unit's dedicated Start-Up team will work with study sponsors to coordinate the ethics approval process, the contracts, budgets and associated requirements.

**GMRF is routinely the first site in Australia to gain ethics approval, be initiated and enroll a patient.**

## Regulatory Compliance

The GMRF Clinical Trials Unit maintains audit ready status at all times.

In addition to operating in full compliance with ICH-GCP and the TGA guidelines on Good Clinical Practice, the Unit operates under a complete set of internal Standard Operating Procedures.

Regular internal audits ensure study protocol and SOP compliance and ensure the integrity of the data presented to our Sponsors.

**Successful audit outcome by the European Medicines Agency (EMA) in 2015 and the Food and Drug Administration (FDA) in 2017**

# Participating in a Trial at GMRF

## Participants

Potential participants are referred to the unit by the Study Investigators as well as external doctors and other hospitals. GMRF will also advertise for clinical trial participants as required.

GMRF's Clinical Trials Unit has an excellent record of exceeding recruitment targets.

GMRF regularly collaborates with patient advocacy groups to help further their understanding of clinical trials and promote access to clinical trials. The GMRF website lists the trials currently open to recruitment and is also listed on the Australian Clinical Trials website.

**"I have been exceptionally well supported on this trial. I know the welfare of the patient is the first priority."**

Howard, Clinical Trial Participant

**Find out more at www.gallipoliresearch.com.au/CTU**

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## Contact Us


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