

Enhancing clinical trial activity, access and involvement
to improve the lives of people with pulmonary fibrosis

Prospectus



PACT

PF Australasian Clinical Trials

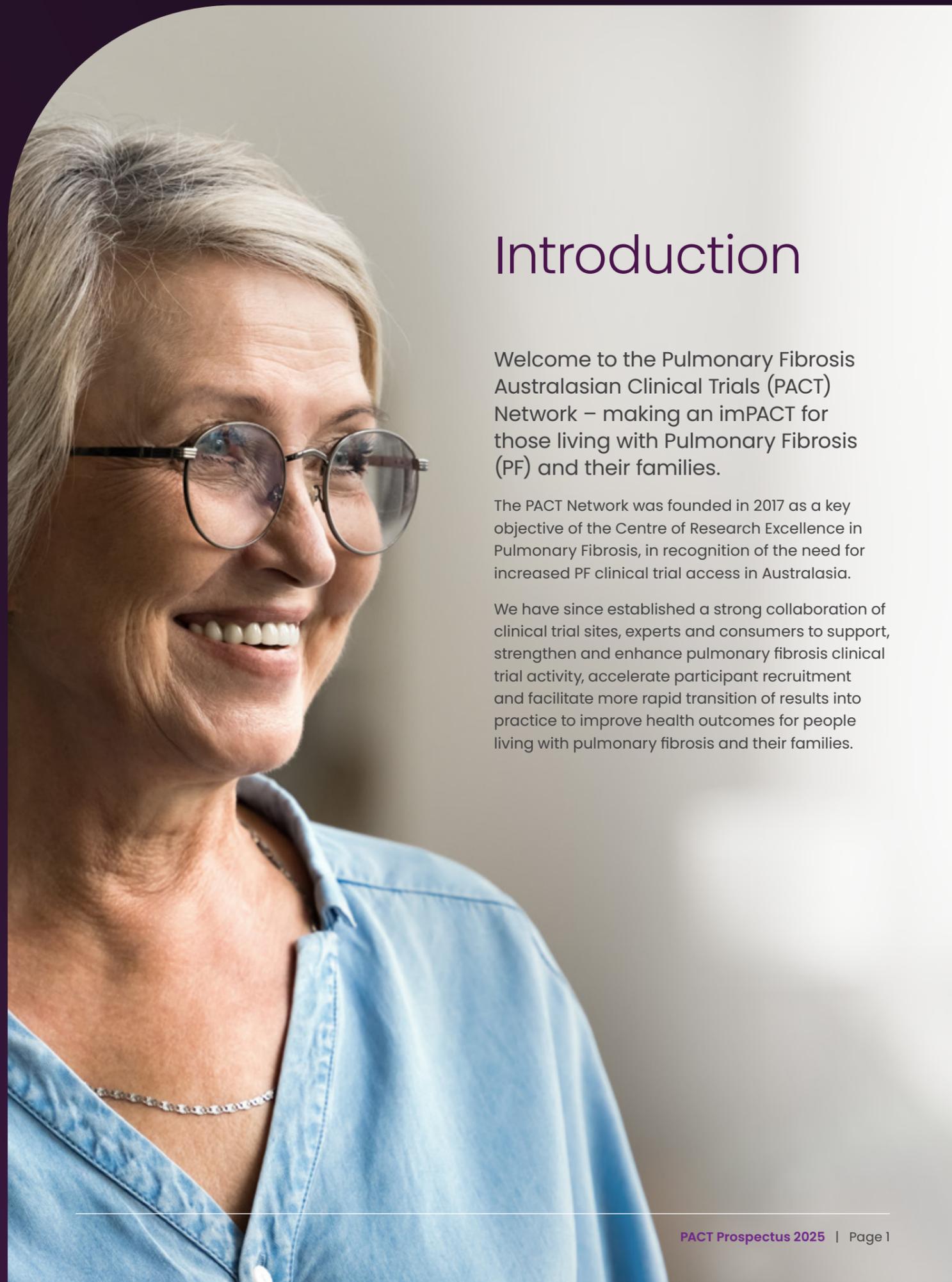


Making an imPACT

PACT – A leading clinical trial network strengthening pulmonary fibrosis clinical trial activity and capacity, improving patient trial access and accelerating participant recruitment across Australia and New Zealand.



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Introduction

Welcome to the Pulmonary Fibrosis Australasian Clinical Trials (PACT) Network – making an imPACT for those living with Pulmonary Fibrosis (PF) and their families.

The PACT Network was founded in 2017 as a key objective of the Centre of Research Excellence in Pulmonary Fibrosis, in recognition of the need for increased PF clinical trial access in Australasia.

We have since established a strong collaboration of clinical trial sites, experts and consumers to support, strengthen and enhance pulmonary fibrosis clinical trial activity, accelerate participant recruitment and facilitate more rapid transition of results into practice to improve health outcomes for people living with pulmonary fibrosis and their families.

About Us

We are a diverse network of accomplished multi-disciplinary clinical trial experts from across Australia and New Zealand: including medical practitioners, nurses, allied health, scientists, consumer representatives and industry.

As clinical trial leaders, we are committed to driving pulmonary fibrosis clinical trial activity and improving trial access across Australasia to advance the development of new knowledge and treatments to improve and save lives.

Our Mission

Our mission is to facilitate high-quality Australasian clinical trial activity in pulmonary fibrosis, thereby maximising local capacity for the development of therapies that reduce morbidity and mortality and enhance quality of life for people living with pulmonary fibrosis.

Our People

The PACT Network is a collaboration of active and highly experienced clinical trial and research leaders, coordinators and investigators. We have more than 30 sites across Australia and New Zealand currently participating in PACT endorsed trials.

Our PACT Steering Committee members are experts in their field and, along with the PACT central team, support the aims of the PACT Network by designing and delivering multi-centre clinical trials, promoting endorsed trials and driving patient recruitment.

Our Steering Committee Members include:



Prof Ian Glaspole

Prof Glaspole is the Chair of the PACT Network and is an established international expert in clinical trials in interstitial lung disease. His experience dates back to 2004 and the first randomised controlled clinical trial in Australia; since then, he has had continuous activity as an Interstitial Lung Disease (ILD) clinical trialist. He is based at the Alfred Hospital and Monash University School of Translational Medicine where he is supported by highly experienced clinical trial staff and an actively involved participant group. His group performs clinical trials in all phases.



Prof Tamera Corte

Prof Corte is the Director of the ILD service at Royal Prince Alfred Hospital, Sydney and large ILD clinical trials unit. She is the national lead for the Centre of Research Excellence for Pulmonary Fibrosis, Australasian ILD registry, and biobank and lead of her own PF clinical and translational research program. Prof Corte co-established the Pulmonary Fibrosis Australasian Clinical Trials (PACT) Network. She has been a principal investigator for more than 40 commercially sponsored ILD clinical trials, and currently sits on many global clinical trial steering committees.

Our People continued



Prof Dan Chambers

Prof Chambers is a thoracic transplant physician, interstitial lung disease expert and clinical trialist. He is a Professor of Medicine at The University of Queensland, and heads one of the world's largest clinical trials programs in lung fibrosis. Prof Chambers is a global leader in investigator-led and commercially sponsored interventional clinical trials in ILD and leads multiple national research collaboratives. He has been Australian principal investigator for multiple trials and has sat on several global Steering Committees.



Prof Anne Holland

Prof Holland is a global leader in clinical trials of non-drug interventions. She has led over 20 randomised controlled trials to completion, including trials of exercise and self-management interventions for people with chronic lung disease. Prof Holland leads a network of investigators across 4 countries (Australia, Sweden, United Kingdom and Brazil) and over 20 clinical trial sites.



A/Prof Nicole Goh

A/Prof Goh is an established international expert in clinical trials in ILD. A/Prof Goh established the interstitial lung disease service at the Austin Hospital and her clinical cohort at the Austin Hospital has been used to support numerous interventional trials in collaboration. She has been a principal investigator for several pharmaceutical clinical trials.



A/Prof Lauren Troy

A/Prof Troy is a key figure in ILD research in Australia and is internationally recognised for her contributions to ILD diagnostics. She has specific experience in multi-centre clinical trial design and conduct and is principal investigator on a number of international pharmaceutical trials in ILD.

Since its inception, the aim of PACT has been to support and deliver high-quality PF clinical trials in order to advance research and improve patient outcomes.



Dr. John Mackintosh

Dr. Mackintosh is a respiratory and lung transplant physician with extensive phase 1-3 clinical trials experience. Through his role as chair of the Queensland Statewide ILD Multi-Disciplinary Meeting, he services a large geographic area, translating into strong clinical trial recruitment.



Karen Symons

Karen is an ILD Nurse Specialist and has been working in Respiratory Medicine for over 30 years and specifically in ILD since 2008. Karen coordinates both translational and therapeutic clinical trials in IPF and ILD and coordinates an ILD outpatient service.



Jess Rhodes

Jess is a Clinical Nurse Consultant working within an ILD Clinical Trials Team. She has extensive experience as a clinical trial coordinator for industry sponsored clinical trials and investigator led trials. Jess has a special interest in improving accessibility to trials for patients of all backgrounds.



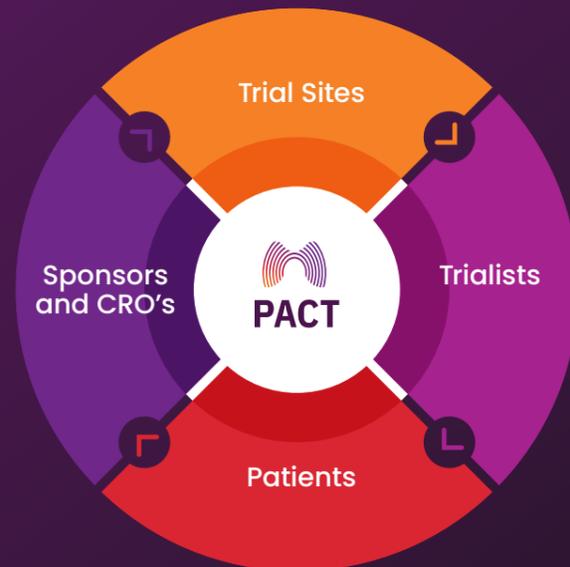
Jennifer Walsh

Jennifer is the PACT Executive Officer and supports PACTs central operational activities, as well as the coordination of the various PACT strategic projects. She has extensive research experience with several chronic diseases, and has managed various research studies, including multi-centre randomised controlled trials at the University of Sydney, UNSW and Cancer Council Victoria.

Dr Harry Gallagher

Dr Gallagher is a Respiratory physician and is Head of the Respiratory Department at Waikato Hospital, Te Whatu Ora Health New Zealand. Harry completed a clinic fellowship in lung transplant and pulmonary vascular diseases at The Prince Charles Hospital, Brisbane. Harry has an interest in promoting interstitial lung disease research in New Zealand.

What we do



With our established network of trialists, clinical trial support teams and PACT members with lived experience, we provide a streamlined link between sponsors and Australasian trialists, sites and patients.

By facilitating access to our network and membership base, PACT can expedite site identification and collaboration for trial start-up and operation through:

- 1 Facilitated access to our network of trialists and more than 30 trial-ready sites across Australia and New Zealand.
- 2 Trial recruitment assistance, with direct access to leading Australasian trial sites and over 6000 patients.
- 3 Access to the PACT Australasian PF Trial Site Feasibility Index, our world leading platform that provides sponsors with rapid and tailored recognition of potential trial sites, and enhanced visibility to PF trial sites trial site visibility
- 4 PACT clinical trial endorsement, enhancing the acceptability of protocols to investigators, referrers and study participants, and adding to the competitiveness of grant applications.
- 5 Promotion of endorsed trials via our 'Find a Trial' webpage and across our extensive network of health professionals and people with lived experience.
- 6 Access to PACT Members with lived experience and the CRE-PF Consumer Advocacy Group. PACT supports and facilitates consumer input and involvement through all stages of research, including development of research questions, research design and choice of patient-relevant outcomes, review of patient-facing research materials such as flyers and consent forms.

Our PACT Trial Support Innovations

The Australasian PF Trial Site Feasibility Index

This unique, PACT-developed innovation is a centralised, web-based repository of comprehensive site feasibility data routinely updated by more than 30 trial sites across our Australasian network.

It is designed to:

- Remove the requirement for repeated completion of feasibility questionnaires, reducing trial site workloads and follow-up for sponsors, CROs and investigators;
- Increase trial site visibility to study sponsors and clinical research organisations, maximising opportunities for trial sites and patients to be offered trial participation;
- Enhance opportunities for sites outside large metropolitan hospitals to participate in PF trials;
- Provide rapid and comprehensive access for study sponsors and CRO's to Australasia's PF trial sites, shortening the time to trial initiation;
- Guide trial site contact so that sponsors and CROs can easily recognise sites most likely to be feasible for their planned trial.

PACT Trial Endorsement

PACT is committed to facilitating high-quality, high-impact clinical research to improve patient outcomes and advance clinical care through contribution to the evidence base.



Our endorsement policy has been developed to ensure that PACT endorsement is synonymous with a consistently high standard of study design, conduct, analysis, publication, and dissemination, and with optimal research capacity and study feasibility. Maintenance of such high quality ensures that PACT endorsement of a study and its outputs is considered a 'gold standard'.

PACT endorsement is a validation of high-quality research.

PACT endorsed trials are promoted via our website as well as by direct communications to our health professional network and to PACT members through e-newsletters and social media.

PACT Website and Patient Trial Enquiry Management

Our state-of-the-art website includes our PACT endorsed trial listing webpage with individual, tailored trial information.

Patient and carer trial participation enquiries that are submitted via our website are managed by the PACT team who assess potential participant suitability for current trials and liaise with appropriate trial sites to facilitate participant access.

Our Strategic Direction



PACT is enhancing clinical trial activity, access and involvement by:

1. Expanding the PF clinical trial portfolio through initiatives such as:

- Support of investigator-driven research through peer review via PACT endorsement;
- Support of pharma-sponsored research by advocating for it to be conducted in Australasia and assisting sponsors/CROs in identifying suitable trial sites.

2. Improving access to information and increased awareness of PF research by:

- Provision of comprehensive PF clinical trial information via the PACT website, connecting patients to sites and recruiting studies;
- Implementation of strategies for effective consumer involvement in PACT activities, such as grant reviews.

3. Upskilling the clinical trials workforce via:

- Implementation of PACT's innovative training and education programs for trialists and clinical trial coordinators;
- Health professional educational resources available via PACT website.

4. Developing early-phase clinical trial units through the:

- Identification and development of strategies to overcome barriers to early phase trial site establishment;
- Support of current early phase trial sites.

5. Supporting trial access for those outside metropolitan areas by:

- Identifying barriers to trial access outside of metropolitan centres and developing strategies to reduce these;
- Establishing a PACT PF Tele-trials model.

6. Developing novel approaches to shorten timelines and broaden the PF clinical trials pipeline. We are:

- Identifying novel trial methodologies and innovative trial design to expedite outcomes through collaborations;
- Building capacity in innovative trial design for PF through education and training.

Become a PACT Member

PACT welcomes new members from every sphere of pulmonary fibrosis research, care and life with the condition. If you are not already part of our growing pulmonary fibrosis community, please join us!

Membership benefits include:

- Engagement with our network of dedicated multi-disciplinary professionals across Australia and New Zealand; including medical practitioners, nurses, allied health, scientists, consumer representatives and industry;
- Access to support for development of investigator-initiated studies, from concept to protocol and study conduct;
- Opportunity to hear about cutting-edge clinical trials and other research, as well as advocate for those with lived experience;
- Notification of upcoming PACT education seminars and webinars;
- Access to PACT research award and grant opportunities.

To complete a PACT Membership application, please visit our website.

For additional information or questions, please contact:

Ms Jennifer Walsh – PACT Executive Officer

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The University of Sydney NSW 2050

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To read more about PACT, please visit our website
www.pactnetwork.com.au.



PACT

PF Australasian Clinical Trials

Our Founding Institutions and Partners

Thank you to our institutions, partners and collaborators for their continued support of the Network.



Centre of Research Excellence in
Pulmonary Fibrosis

