



## **INTRODUCTION**

The Pulmonary Fibrosis Australasian Clinical Trials (PACT) Network is a collaboration uniting the Centre for Research Excellence in Pulmonary Fibrosis, leading pulmonary fibrosis specialists, and Lung Foundation Australia, to support, design and deliver high quality clinical trials and studies that will provide hope and improved outcomes for people living with pulmonary fibrosis.

Participation in clinical trials drives innovation and best practice in healthcare by generating the evidence which guides sound decision making. A group of expert clinicians from the Centre for Research Excellence in Pulmonary Fibrosis recognised that pulmonary fibrosis research lagged other serious lung conditions and responded by forming the PACT network in 2017. PACT's overarching objective is to ensure people living with pulmonary fibrosis, their families and health care professionals are aware of, and have access to, up-to-date clinical trial information and enable participation in a broad range of clinical trials.

## **VISION**

To be a leading Pulmonary Fibrosis Clinical Trials Network that will:

- Facilitate the development of an optimal environment for the performance of high-quality clinical trials in Australia and New Zealand, leading to safe and effective therapies in pulmonary fibrosis.
- Build and enhance Australasian and international collaborations with all stakeholders in clinical trial performance and participation.

## **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.

## **CORE VALUES**

- Collaboration, collegiality.
- Alignment of the best interests of researchers, health professionals and patients.
- Development of sustainable and shared infrastructure to improve trial quality and feasibility.
- Integrity, innovation, best practice.



## **OBJECTIVE 1. EXPAND PULMONARY FIBROSIS CLINICAL TRIAL PORTFOLIO**

### STRATEGIES

- Support investigator-driven pulmonary fibrosis research through peer review and facilitating collaboration.
- Support pharma-sponsored research through advocating for Pulmonary Fibrosis research to be conducted in Australasia and assisting sponsors/CROs in identifying suitable trial sites.
- Enhance phase 1 trial capability for pulmonary fibrosis to accelerate drug development.
- Develop and administer PACT Network trial grants/awards.
- Identify areas of need in pulmonary fibrosis care and actively seek trial concepts in these areas.
- Identify and address barriers to trial setup.
- Establish and implement processes for prioritisation of research questions.
- Embed trial processes within delivery of routine healthcare.

## **OBJECTIVE 2. ENGAGE WITH CONSUMERS TO IMPROVE ACCESS TO CURRENT INFORMATION AND INCREASE AWARENESS ABOUT PULMONARY FIBROSIS CLINICAL RESEARCH IN AUSTRALASIA.**

### STRATEGIES

- Extensive and up-to-date PF clinical trial information available via PACT website.
- Undertake active expansion of PACT consumer membership.
- Scale up and broaden consumer representation and input into clinical trials research.
- Develop and implement strategies for effective consumer involvement in PACT activities.
- Engage the CRE-PF consumer advisory group to provide feedback and input on PACT activities as required.
- Develop resources to guide consumer clinical trial participation.
- Implement effective communication strategies with PACT consumer members.



### **OBJECTIVE 3. SUPPORT TRIAL ACCESS FOR THOSE OUTSIDE METROPOLITAN AREAS.**

#### STRATEGIES

- Identify and develop strategies to reduce barriers to trial access outside metropolitan areas.
- Focus on improving trial access for populations across various geographic locations.
- Establish PF Tele-trials model.
- Development of tele-trials uptake for pulmonary fibrosis studies.
- Align with existing networks such as ACTA and The Australian Tele trials Program to support understanding and reduction to barriers to trial access and utilise existing resources and programs.

### **OBJECTIVE 4. ENHANCE COLLABORATIONS IN PULMONARY FIBROSIS CLINICAL TRIALS.**

#### STRATEGIES

- Expansion of PACT health professional membership, especially where expertise gaps may exist.
- Identify projects that can be conducted in collaboration with other networks in Australia and New Zealand.
- Increase collaboration with relevant national and international groups.
- Collaborate with international Clinical Trial Networks (Australasian-initiated trials or internationally initiated trials).
- Participate in clinical trials developed by similar international networks.
- Continue relationships with major relevant fundraising bodies.
- Identify and decrease barriers to multidisciplinary research.
- Joint grant applications.

### **OBJECTIVE 5. DEVELOPMENT OF AUSTRALASIAN EARLY-PHASE CLINICAL TRIAL UNITS AND UPSKILLING OF THE CLINICAL TRIALS WORKFORCE.**

#### STRATEGIES

- Identify and develop strategies to overcome barriers to early phase trial site establishment.
- Support current early phase trial sites.
- Develop innovative training and education programs for trialists.
- Develop health professional educational resources available via PACT website.



**OBJECTIVE 6. DEVELOPMENT OF NOVEL APPROACHES TO SHORTEN TIMELINES  
AND BROADEN THE PF CLINICAL TRIALS PIPELINE.**

STRATEGIES

- Develop novel trial methodology and innovative clinical trial design to expedite trial outcomes, as well as adaptive clinical trial designs through collaborations with partners, for example the RE-BUILD Group.
- Build capacity in innovative trial design for PF.
- Facilitate application of adaptive trial design to PF research.
- Advocate for improved approval pathways (for example, mutual recognition and streamlined RGO processes).

**MEASURING OUR SUCCESS**

	Objectives	Initiatives	Key Indicators
1	Expand Pulmonary Fibrosis clinical trial portfolio	<ul style="list-style-type: none"> <li>• Support investigator-driven pulmonary fibrosis research through peer review and facilitating collaboration.</li> <li>• Support pharma-sponsored research through advocating for Pulmonary Fibrosis research to be conducted in Australasia and assisting sponsors/CROs in identifying suitable trial sites.</li> <li>• Develop and administer PACT Network trial grants/awards.</li> </ul>	<ul style="list-style-type: none"> <li>• PACT Network Endorsement applications.</li> <li>• Number of new and innovative trials commenced.</li> <li>• Number of grants administered.</li> <li>• Publications.</li> </ul>
2	Engage with consumers to improve access to current information and increase awareness about pulmonary fibrosis	<ul style="list-style-type: none"> <li>• Extensive and up-to-date PF clinical trial information available via PACT website.</li> <li>• Scale up and broaden consumer representation and input into clinical trials research.</li> </ul>	<ul style="list-style-type: none"> <li>• Web traffic and information download metrics.</li> <li>• Consumer enquiries.</li> <li>• Increased consumer representation in PACT activities.</li> </ul>



	clinical research in Australasia.		<ul style="list-style-type: none"> <li>Increased consumer participation in pf clinical trials.</li> </ul>
3	Support trial access for those outside metropolitan areas.	<ul style="list-style-type: none"> <li>Focus on improving trial access for populations across various geographic locations.</li> <li>Establish PF Tele-trials model.</li> </ul>	<ul style="list-style-type: none"> <li>PACT PF tele-trials model established.</li> <li>New PF tele-trials being undertaken.</li> <li>Broader consumer representation in clinical trials.</li> </ul>
4	Enhance collaborations in pulmonary fibrosis clinical trials.	<ul style="list-style-type: none"> <li>Identify projects that can be conducted in collaboration with other networks in Australia and New Zealand.</li> <li>Increase collaboration with relevant national and international groups.</li> </ul>	<ul style="list-style-type: none"> <li>New Partnerships.</li> <li>Number of collaborative agreements.</li> <li>New projects and trials established.</li> </ul>
5	Development of Australasian early-phase clinical trial units and upskilling of the clinical trials workforce.	<ul style="list-style-type: none"> <li>Support current early phase trial sites.</li> <li>Develop innovative training and education programs for trialists</li> </ul>	<ul style="list-style-type: none"> <li>Establishment of Trial Site directory.</li> <li>Establishment of PACT Training Program.</li> <li>Number of trainees achieving PACT Training Program certification.</li> </ul>
6	Development of novel approaches to shorten and broaden the pf clinical trials pipeline.	Collaborations to develop novel trial methodology and innovative clinical trial design to expedite trial outcomes, including the use of digital applications for consent, randomisation and trial management, and adaptive clinical trial designs.	<ul style="list-style-type: none"> <li>Number of innovative trials developed and commenced.</li> <li>Publications.</li> </ul>