

## PACT – Patient New Clinical Trial and Research

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Trial title	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52 weeks in patients with Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)
Trial synopsis	<p>Interstitial Lung Disease (ILD) results from fibrosis (thickening and scarring of the lung tissue). This makes it difficult to breathe and for the lungs to take up oxygen. Current treatments target this thickening of the lung tissue and they are called anti-fibrotic medication, slowing the progression of fibrosis. Other treatments target the inflammation, which is sometimes caused by autoimmune disorders, these drugs suppress the immune system to lower inflammation.</p> <p>BI 1015550 is an oral medication which inhibits a protein called PDE4B. Inhibition of PDE4B has been shown to reduce inflammation and fibrosis, thereby improving lung function. In people who have PF-ILDs, breathing and shortness of breath will get worse over time. The purpose of this study is to test the safety, effectiveness, and side effects of 2 different doses of BI 1015550 compared to placebo, in participants with PF-ILDs. BI 1015550 will be taken as a tablet twice a day and is expected to improve lung function.</p>
Investigational medicinal product	BI 1015550
Disease target	Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs)
Sponsor	Boehringer Ingelheim
Duration	<p>Part A - 52-weeks</p> <p>Part B – until last participant globally reaches 52-weeks</p>
Trial Status	Recruiting
Lead site(s) in Australia	Lung Research Queensland
Lead site(s) in New Zealand	Aotearoa Clinical Trials
Additional sites	<p>Australia:</p> <ul style="list-style-type: none"> <li>• Alfred Hospital</li> <li>• Austin Hospital</li> <li>• Lung Research Victoria</li> <li>• Mater Hospital – Brisbane</li> <li>• Princess Alexandra Hospital</li> <li>• The Prince Charles Hospital</li> <li>• TrialsWest</li> <li>• Fiona Stanley Hospital</li> <li>• Royal Adelaide Hospital</li> <li>• Canberra Hospital</li> </ul>



	<ul style="list-style-type: none"><li>• Royal Prince Alfred Hospital</li><li>• Westmead Hospital</li><li>• Macquarie University</li></ul> New Zealand: <ul style="list-style-type: none"><li>• Greenlane Clinical Centre</li><li>• Waikato Hospital</li><li>• Tauranga Hospital</li></ul>
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