Clinician - PACT
New Clinical Trial and Research

Trial title	A randomised, double-blind, placebo-controlled parallel group study in IPF patients over 12 weeks evaluating efficacy, safety and tolerability of BI 1015550 taken orally.
Trial synopsis	This phase II trial is a double-blind, placebo-controlled comparison of BI 1015550 18 mg b.i.d. over 12 weeks in patients treated with antifibrotic treatment or not treated with antifibrotic treatment at baseline. Patients randomised into the trial will be treated for 12 weeks. The patients will be included in the trial and during the screening period (up to 44 days), the eligibility criteria will be assessed. After this period, the eligible patients will be randomised in the trial in a 2:1 ratio (BI 1015550 18 mg b.i.d/placebo b.i.d). This phase II trial will investigate the efficacy of BI 1015550 18mg b.i.d. by comparing the change from baseline in Forced Vital Capacity (FVC) after 12 week of treatment compared to placebo. This trial will also evaluate the safety and tolerability of BI 1015550 over 12 weeks compared to placebo where antifibrotic treatment is introduced. BI 1015550 will be evaluated as a stand-alone treatment in patients or in addition to background antifibrotic treatments, i.e. this trial will include patients with or without approved and available antifibrotic treatment (nintedanib or pirfenidone) at baseline and during the study. New treatments are needed that further reduce the decline in FVC positively affect symptoms and improve quality of life in patients with Idiopathic Pulmonary Fibrosis.
Investigational medicinal product, comparator and randomisation	2:1 ratio (BI 1015550 18 mg / placebo)
Disease target	Idiopathic Pulmonary Fibrosis
Sponsor	Boehringer Ingelheim
Duration	12 weeks
Trial Status	Recruiting
Trial phase	Phase II
Key inclusion criteria	• Patients aged ≥ 40 years. • IPF diagnosis confirmed by central review.

	• FVC ≥ 45% • DLCO ≥25% and <80% • Either stable treatment with antifibrotics for at least 8 weeks prior to Visit 1or not treated with antifibrotics for at least 8 weeks prior to Visit 1.
Key exclusion criteria	• Relevant airways obstruction (pre-bronchodilator FEV1/FVC <0.7) at Visit 1. • Acute IPF exacerbation within 4 months prior to screening and/or during the screening period • Lower respiratory tract infection requiring antibiotics within 4 weeks prior to Visit 1 and/or during the screening period. • Any suicidal behaviour in the past 2 years • Any suicidal ideation of type 4 or 5 on the C-SSRS in the past 3 months or at Visit 1. • Baseline condition or medical history of vasculitis • Confirmed infection with SARS-Cov-2 wihtin 4 weeks prior to visit 1 or during screening period.
Primary endpoint	The primary endpoint is the change from baseline in FVC at 12 weeks (in mL).
Number of participants sought	150
Lead site(s) in Australia	Dr Ian Glaspole – The Alfred Hospital, Melbourne, VIC
Lead site(s) in New Zealand	NA
Additional sites	Royal Prince Alfred Hospital, Sydney, NSW.
Contact person	pactcoordinator@cre-pf.org.au