

Data Sharing Request Due Diligence Assessment

General Information	
YODA Project (Protocol) ID:	2025-0300
Date Proposal Received by YODA Project:	2-MAY-2025
Product Name(s):	Bosentan (TRACLEER®) Macitentan (OPSUMIT®)
Condition(s) Studied:	Idiopathic Pulmonary Fibrosis Pulmonary Fibrosis Scleroderma, Systemic
NCT Numbers(s), Protocol Number(s) and Title(s):	<ol style="list-style-type: none"> 1. NCT00391443 - AC-052-321 Effects of Bosentan on Morbidity and Mortality in Patients With Idiopathic Pulmonary Fibrosis - a Multicenter, Double-blind, Randomized, Placebo-controlled, Parallel Group, Event-driven, Group Sequential, Phase III Study 2. NCT00071461 - AC-052-320 (BUILD 1) A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy, Safety, and Tolerability of Bosentan in Patients With Idiopathic Pulmonary Fibrosis, Open Label Extension 3. NCT00631475 - AC-052-322 Open-Label Extension Study in Patients With Idiopathic Pulmonary Fibrosis Who Completed Protocol AC-052-321 (NCT00391443) 4. NCT00070590 - AC-052-330 (BUILD 2) A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy, Safety and Tolerability of Bosentan in Patients With Interstitial Lung Disease Associated With Systemic Sclerosis 5. NCT00903331 - AC-055B201 A Double-blind, Randomized, Placebo-controlled, Multicenter, Parallel Group Study to Evaluate the Efficacy, Safety, and Tolerability of Macitentan in Patients With Idiopathic Pulmonary Fibrosis
Proposal Review	
Question 1: The clinical trial data from the study/studies listed above were previously identified and approved as being available for a data sharing request. Is there any reason why the study/studies listed should no longer be shared?	No
Comments if 'Yes':	
Question 2: On review of the proposal, is there any data that has been requested that may be missing from the clinical database?	No
Comments if 'Yes':	
Question 3: Is a similar analysis underway, or completed and pending disclosure by J&J?	No
Comments if 'Yes':	