294 Patients were assessed for eligibility

148 Were excluded
116 Did not meet eligibility criteria
22 Withdrew consent
8 Were eligible, but were not enrolled
2 withdrawn consent by legally authorized representative

146 Underwent randomization

73 Were assigned to the Pirfenidone group
73 Were included in the safety population

73 Were assigned to the stand- treatment group
2 Died
71 Were included in the safety population