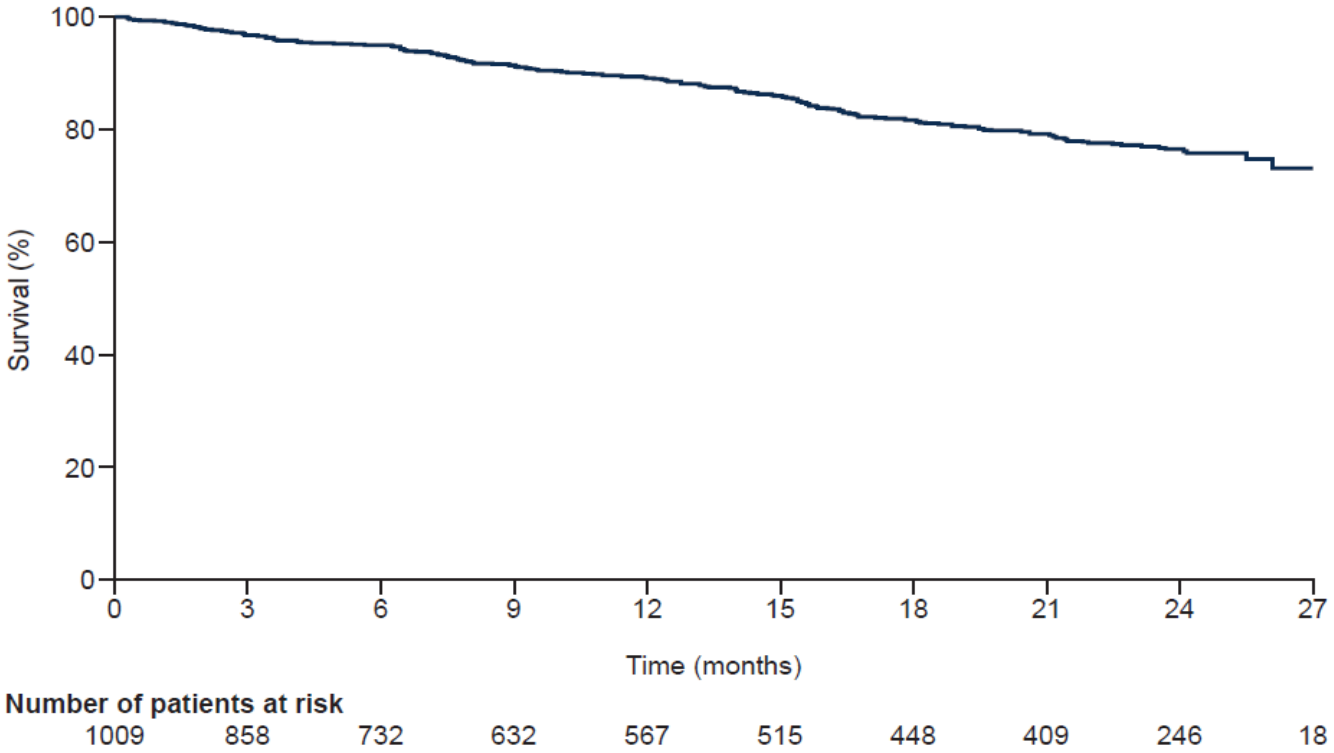
Supplementary materials

SUPPLEMENTARY FIGURE S1 Kaplan Meier of survival in the overall population[#]



[#]: Only deaths that were an outcome of an ADR or were the primary reason for study discontinuation were collected.

SUPPLEMENTARY TABLE S1 Early discontinuation of pirfenidone in the overall population by country

	France (n=214)	**Germany (n=452)**	**UK (n=184)**	**Other (n=159)**
Number of patients who discontinued, n (%)	148 (69.2)	289 (63.9)	146 (79.3)	72 (45.3)
Death	21/148 (14.2)	78/289 (27.0)	34/146 (23.3)	27/72 (37.5)
ADR[#]	76/148 (51.4)	108/289 (37.4)	69/146 (47.3)	29/72 (40.3)
Other	51/148 (34.5)	103/289 (35.6)	43/146 (29.5)	16/72 (22.2)
Overall median (IQR) time to discontinuation, days	249.0 (90.0–461.0)	176.0 (60.0–401.0)	201.5 (88.0–398.0)	210.5 (70.0–435.0)

ADR: adverse drug reaction; IQR: interquartile range. [#]: An ADR was defined as any safety event with a possible causal relationship to pirfenidone. The treating physician (investigator) made a clinical judgement to decide if the ADR was related to pirfenidone.

SUPPLEMENTARY TABLE S2 ADRs[#] in the overall population by country

	France (n=214)	**Germany (n=452)**	**UK (n=184)**	**Other (n=159)**	**Total (N=1009)**
Any ADR[¶], n (%)	176 (82.2)	314 (69.5)	139 (75.5)	112 (70.4)	741 (73.4)
Nausea	34 (15.9)	97 (21.5)	38 (20.7)	39 (24.5)	208 (20.6)
Fatigue	33 (15.4)	83 (18.4)	41 (22.3)	30 (18.9)	187 (18.5)
Decreased appetite	44 (20.6)	62 (13.7)	39 (21.2)	18 (11.3)	163 (16.2)
Decreased weight	62 (29.0)	50 (11.1)	35 (19.0)	14 (8.8)	161 (16.0)
Rash	26 (12.1)	52 (11.5)	28 (15.2)	17 (10.7)	123 (12.2)
Diarrhoea	26 (12.1)	29 (6.4)	30 (16.3)	11 (6.9)	96 (9.5)
Dizziness	15 (7.0)	29 (6.4)	9 (4.9)	12 (7.5)	65 (6.4)
Photosensitivity reaction	23 (10.7)	19 (4.2)	8 (4.3)	9 (5.7)	59 (5.8)

ADR: adverse drug reaction. [#]: An ADR was defined as any safety event with a possible causal relationship to pirfenidone.The treating physician (investigator) made a clinical judgement to decide if the ADR was related to pirfenidone. [¶]: Most common ADRs (≥5% of total number of patients).

SUPPLEMENTARY TABLE S3 Dose adjustments in the overall population

	Patients, n (%)
Patients that had at least one dose adjustment[#]	373 (37.0)
Dose reduction[¶]	259 (25.7)
Temporary[†]	132 (13.1)
Permanent[†]	160 (15.9)
Dose interruption[§]	163 (16.2)

[#]: A dose adjustment was considered to be at least one dose reduction and/or dose interruption in the treatment course of a patient. [¶]: A dose reduction was considered to be at least one temporary and/or permanent reduction in dose during the treatment course of a patient. [†]: A patient may have had a temporary dose reduction initially, and a subsequent permanent reduction. A dose reduction was considered temporary if the dose changed further, whereas it was considered permanent if the patient ended the study at the reduced dose. [§]: A dose interruption occurred when treatment was temporarily discontinued for ≥1 day and subsequently restarted.

SUPPLEMENTARY TABLE S4 ADRs[#] with a fatal outcome in the overall population

ADR	Patients, n (%)
Patients with an ADR with a fatal outcome	6 (0.6)
Cardiac arrest	1 (0.1)
Cardiac failure	1 (0.1)
Acute respiratory distress syndrome	1 (0.1)
Pulmonary embolism	1 (0.1)
Pneumonia	1 (0.1)
Decreased weight	1 (0.1)

ADR: adverse drug reaction. [#]: An ADR was defined as any safety event with a possible causal relationship to pirfenidone. The treating physician (investigator) made a clinical judgement to decide if the fatal outcome, as a result of an ADR was related to pirfenidone.