Participant Flow

Figure 1. Subject Disposition

Provided Informed Consent
N=29

↓

Downloaded the Study App
N=28

→ Withdrawn
N=1 (Died)

↓

Completed the Diary Phase
N=27

↓

Invited to Qualitative Interviews
N=22

→ Unavailable for Interview
N=1

↓

Completed Qualitative Interview
N=21
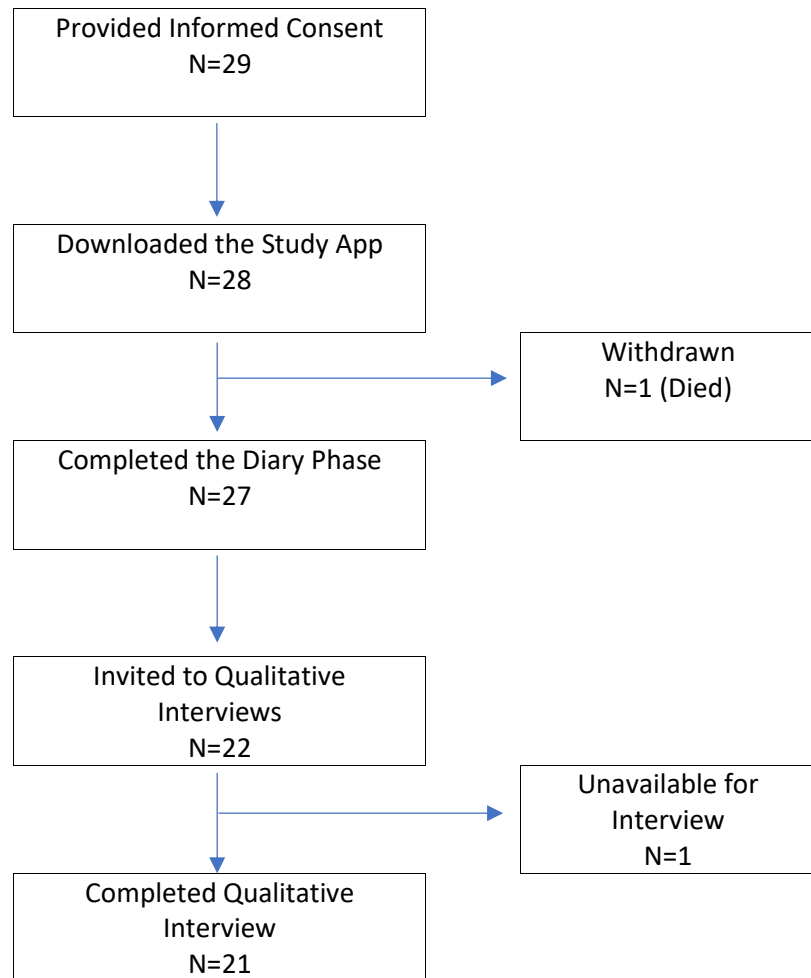
Baseline Characteristics

Table 1: Demographics and baseline characteristics

Characteristic	Parameter	All Subjects (N=28)
Sex		
Male	n (%)	20 (71.4)
Female	n (%)	8 (28.6)
Age at screening	Mean (SD)	72.4 (7.29)
	Median (range)	73.5 (55, 84)
	SE	1.38
Cough Severity NRS score at screening	Mean (SD)	6.4 (1.79)
	Median (range)	6.5 (4, 10)
	SE	0.34
Concomitant pirfenidone		
Yes	n (%)	6 (21.4)
No	n (%)	22 (78.6)
Concomitant nintedanib		
Yes	n (%)	7 (25.0)
No	n (%)	21 (75.0)

N=total number of subjects; n=number of subjects; NRS=numerical rating scale; SD=standard deviation; SE=standard error

Outcome Measures

Table 2. Weekly Cough Severity NRS Score (Primary Endpoint)

Time Point	Parameter	All Subjects (N=28)	
		Absolute	**Change from Week 1**
Week 1	n	27	NA
	Mean (SD)	5.07 (1.777)	
	Median (range)	4.86 (1.6, 8.2)	
Week 2	n	26	26
	Mean (SD)	5.00 (2.276)	-0.10 (1.453)
	Median (range)	5.10 (0.0, 8.3)	0.29 (-6.0, 1.7)

Weekly NRS is the average of the scores provided over the 7 days of each week. At least 4 non-missing daily scores over the 7 days are needed for this to be derived.
N=total number of subjects; n=number of subjects; NA=not applicable; NRS=numerical rating scale; SD=standard deviation

Table 3. Weekly Cough Severity NRS Score - Intraclass Correlation Coefficient Between Weeks 1 & 2

Weekly Summary Statistic	Parameter	Population	
		Full Analysis Set (N=28)	**Subjects with the Same GRS Score in Both Weeks** (N=17)
Mean	n	26	17
	ICC	0.76	0.93
	95% CI	0.56, 0.88	0.83, 0.97
Median	n	26	17
	ICC	0.77	0.92
	95% CI	0.58, 0.89	0.81, 0.97

Mean Weekly NRS is the average of the scores provided over the 7 days of each week. Median is the summary of the scores provided over the 7 days of each week. At least 4 non-missing daily scores over the 7 days were needed for this to be derived.
CI=confidence interval; GRS=Global Rating of Severity; ICC=Intraclass Correlation Coefficient; N=total number of subjects; n=number of subjects; NRS=numerical rating scale

Table 4. Summary of Global Rating of Severity in Weeks 1 and 2

Category	All Subjects (N=28)	
	Week 1	**Week 2**
	n (%)	**n (%)**
Number of subjects completing the assessment	23	25
None	0	1 (4.0%)
Mild	6 (26.1%)	4 (16.0%)

Moderate	10 (43.5%)	15 (60.0%)
Severe	7 (30.4%)	5 (20.0%)

The GRS (None, Mild, Moderate, Severe) has a recall period of 1 week and is asked on the 7th day of each week.
Percentages are based on the number of subjects who provided scores for each week.
GRS=Global Rating of Severity; N=total number of subjects; n=number of subjects

Table 5. Cough Severity VAS Score

Time Point	Parameter	All Subjects (N=28)	
		Absolute	**Change from Week 1**
Week 1, Day 1	n	23	NA
	Mean (SD)	48.6 (19.09)	
	Median (range)	55.0 (7, 87)	
Week 2, Day 7	n	15	14
	Mean (SD)	45.5 (26.10)	-0.3 (20.17)
	Median (range)	46.0 (1, 79)	1.5 (-41, 34)

The VAS is measured from 0 (No coughing) to 100 (Coughing as bad as you can imagine) and scored at Day 1 in Week 1 and Day 7 in Week 2.
N=total number of subjects; n=number of subjects; NA=not applicable; SD=standard deviation; VAS=visual analogue scale

Table 6. Weekly Cough Severity NRS Score by Global Severity Rating

Time Point	Parameter	Global Rating of Severity Category			
		None	**Mild**	**Moderate**	**Severe**
Week 1	n	0	6	10	7
	Mean (SD)	–	3.48 (1.541)	5.52 (1.381)	5.77 (1.885)
	Median (range)	–	3.29 (1.6, 6.0)	5.36 (3.7, 7.6)	5.86 (2.9, 8.2)
Week 2	n	1	4	15	5
	Mean (SD)	0.00	2.29 (0.481)	5.23 (1.779)	7.11 (0.856)
	Median (range)	0.00 (0.0, 0.0)	2.07 (2.0, 3.0)	5.00 (3.1, 8.3)	7.57 (5.7, 7.7)
Overall	n	1	10	25	12
	Mean (SD)	0.00	3.00 (1.333)	5.34 (1.607)	6.33 (1.639)
	Median (range)	0.00 (0.0, 0.0)	2.71 (1.6, 6.0)	5.00 (3.1, 8.3)	6.93 (2.9, 8.2)

Weekly NRS is the average of the scores provided over the 7 days of each week. At least 4 non-missing daily scores over the 7 days were needed for this to be derived.
The GRS (None, Mild, Moderate, Severe) has a recall period of 1 week and is asked on the 7th day of each week.
The subjects may have responded to the GRS question differently at the two assessments and so the number for each category may differ over the 2 weeks.
Overall includes all responses from both Week 1 and Week 2.
GRS=Global Rating of Severity; n=number of subjects; NRS=numerical rating scale; SD=standard deviation

Adverse Events

Not applicable as this was a non-interventional observation study.