Exacerbation-related disutility used in the model

The analyses were carried out using repeated-measures regression models adjusting for FVC%Pred level and including an intercept to reflect the fact that QoL may be influenced by other factors. Treatment was added as an interaction to the disutility and also as a stand-alone covariate in all models but never came out as significant.

The results broken down by treatment shown below come from the model with treatment as a stand-alone covariate.

Exacerbation according to the investigator

Treatment effect not significant: p=0.667 in the "overall" model, p=0.681 in the model looking at 1st month versus subsequent months.

Treatments	Disutility compared to before the exacerbation	Mean	SE	p-value compared to before the exacerbation	95% CI
POOLED	Overall	-0.097	0.028	0.001	-0.152 to -0.042
	In 1st month after exacerbation*	-0.140	0.047	0.003	-0.231 to -0.049
	In subsequent months*	-0.078	0.032	0.016	-0.142 to -0.015
NTD	Overall	-0.092	0.030	0.003	-0.152 to -0.032
	In 1st month after exacerbation	-0.135	0.048	0.005	-0.229 to -0.040
	In subsequent months	-0.074	0.034	0.033	-0.141 to -0.006
PBO	Overall	-0.097	0.028	0.001	-0.152 to -0.042
	In 1st month after exacerbation	-0.140	0.047	0.003	-0.231 to -0.048
	In subsequent months	-0.078	0.032	0.015	-0.142 to -0.015

*Value used in the model

Exacerbation according to the adjudicator

Treatment effect not significant: p=0.696 in the "overall" model, p=0.732 in the model looking at 1st month versus subsequent months.

Treatments	Disutility compared to before the exacerbation	Mean	SE	p-value compared to before the exacerbation	95% CI
POOLED	Overall	-0.136	0.042	0.001	-0.219 to -0.053
	In 1st month after exacerbation*	-0.274	0.059	<0.001	-0.390 to -0.157
	In subsequent months*	-0.033	0.053	0.525	-0.137 to 0.070
NTD	Overall	-0.131	0.044	0.003	-0.218 to -0.044
	In 1st month after	-0.269	0.061	<0.001	-0.388 to -0.150

	exacerbation				
	In subsequent months	-0.029	0.054	0.587	-0.135 to 0.077
PBO	Overall	-0.136	0.042	0.001	-0.219 to -0.053
	In 1st month after exacerbation	-0.273	0.059	<0.001	-0.390 to -0.157
	In subsequent months	-0.033	0.053	0.525	-0.137 to 0.070

*Used in the model