Online Supplement
Validation of the Onset of Effect Questionnaire in Participants With Chronic Obstructive Pulmonary Disease

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The supplemental files are presented to further understand the heterogeneous COPD patient population used in this study. Correlation with Peak Expiratory Flow values are shown. Questionnaires that were specified by the study protocol, but for which data are not shown, include the following: Nighttime Symptoms of COPD Instrument (NiSCI), Exacerbations of Chronic Obstructive Pulmonary Disease Tool – Patient-Reported Outcomes (EXACT-PRO, and PROactive Physical Activity in COPD (C-PPAC).

Table S1. Quantitative Analysis - Participant Demographics

Characteristic	Overall (n = 97)
Age, years	
Mean (SD)	71.3 (7.0)
Median	72.0
Range (min-max)	(53.0-86.0)
IQR (P25-P75)	9.0 (67.0-76.0)
Sex, n (%)	
Male	41 (42.3)
Female	56 (57.7)
Ethnicity, n (%)	
Hispanic or Latino	2 (2.1)
Not Hispanic or Latino	95 (97.9)
Race, ordered by frequency,[a] n (%)	
Indian	1 (1.0)
Black	7 (7.2)
White	90 (92.8)

Characteristic	Overall (n = 97)
Marital status, n (%)	
Single	18 (18.6)
Married	37 (38.1)
Divorced	24 (24.7)
Widowed	16 (16.5)
Other	2 (2.1)
Smoking status, n (%)	
Current	38 (39.2)
Previous	58 (59.8)
Never	1 (1.0)

[a]Not mutually exclusive as one individual reported more than one race.

SD, standard deviation; IQR, interquartile range; P, period.

Table S2. Known-groups Validity for COPD-OEQ Weekly and Daily at Baseline

COPD-OEQ item	Measure	n	LSMean (SE)	*P* value
	COPD-OEQ Weekly			
OEQ 1. You could tell your study medication was working	PGIS			0.3096
	None/mild	27	3.0 (0.2)	
	Moderate	55	2.8 (0.1)	
	Severe/very severe	14	3.3 (0.3)	
	FEV$_1$ improvement			0.4727
	<12%	60	2.9 (0.1)	
	≥12%	37	3.1 (0.2)	
	Morning maximum PEF[a]			0.8314
	Red zone: <200 LPM	43	3.0 (0.2)	
	Yellow zone: 200-320 LPM	23	2.9 (0.2)	
	Green zone: 320-400 LPM	12	3.0 (0.3)	
	Evening maximum PEF[a]			0.0377
	Red zone: <200 LPM	42	3.1 (0.1)	
	Yellow zone: 200-320 LPM	29	3.1 (0.2)	
	Green zone: 320-400 LPM	9	2.2 (0.3)	
	PGIS			0.3842

COPD-OEQ item	Measure	n	LSMean (SE)	*P* value
OEQ 2. You could feel your study medication begin to work right away	None/mild	27	2.6 (0.2)	
	Moderate	55	2.4 (0.1)	
	Severe/very severe	14	2.9 (0.3)	
	FEV$_1$ improvement			0.9653
	<12%	60	2.6 (0.1)	
	≥12%	37	2.5 (0.2)	
	Morning maximum PEF[a]			0.1543
	Red zone: <200 LPM	43	2.6 (0.2)	
	Yellow zone: 200-320 LPM	23	2.4 (0.2)	
	Green zone: 320-400 LPM	12	2.0 (0.3)	
	Evening maximum PEF[a]			0.0111
	Red zone: <200 LPM	42	2.6 (0.2)	
	Yellow zone: 200-320 LPM	29	2.6 (0.2)	
	Green zone: 320-400 LPM	9	1.6 (0.3)	
OEQ 5. You were satisfied with how quickly you felt your study medication begin to work	**PGIS**			0.6145
	None/mild	27	2.9 (0.2)	
	Moderate	55	2.7 (0.1)	
	Severe/very severe	14	2.6 (0.3)	
	FEV$_1$ improvement			0.5384

COPD-OEQ item	Measure	n	LSMean (SE)	P value
	<12%	60	2.7 (0.1)	
	≥12%	37	2.8 (0.2)	
	Morning maximum PEF[a]			0.5658
	Red zone: <200 LPM	43	2.8 (0.2)	
	Yellow zone: 200-320 LPM	23	2.7 (0.2)	
	Green zone: 320-400 LPM	12	2.4 (0.3)	
	Evening maximum PEF[a]			0.0652
	Red zone: <200 LPM	42	2.8 (0.1)	
	Yellow zone: 200-320 LPM	29	2.8 (0.2)	
	Green zone: 320-400 LPM	9	2.0 (0.3)	
COPD-OEQ Daily				
OEQ 1. You could tell your study medication was working	**PGIS**			0.1713
	None/mild	27	3.2 (0.2)	
	Moderate	55	2.8 (0.1)	
	Severe/very severe	13	3.3 (0.3)	
	FEV$_1$ improvement			0.2660
	<12%	60	2.9 (0.1)	
	≥12%	36	3.2 (0.2)	
	Morning maximum PEF[a]			0.0632

COPD-OEQ item	Measure	n	LSMean (SE)	P value
	Red zone: <200 LPM	42	3.2 (0.2)	
	Yellow zone: 200-320 LPM	23	2.9 (0.2)	
	Green zone: 320-400 LPM	12	2.4 (0.3)	
	Evening maximum PEF[a]			0.0003
	Red zone: <200 LPM	41	3.2 (0.1)	
	Yellow zone: 200-320 LPM	29	3.1 (0.2)	
	Green zone: 320-400 LPM	9	1.8 (0.3)	
OEQ 2. You could feel your study medication begin to work right away	**PGIS**			0.3835
	None/mild	27	2.7 (0.2)	
	Moderate	55	2.5 (0.1)	
	Severe/very severe	13	2.8 (0.3)	
	FEV$_1$ improvement			0.0690
	<12%	60	2.5 (0.1)	
	≥12%	36	2.8 (0.2)	
	Morning maximum PEF[a]			0.0747
	Red zone: <200 LPM	42	2.8 (0.2)	
	Yellow zone: 200-320 LPM	23	2.3 (0.2)	
	Green zone: 320-400 LPM	12	2.2 (0.3)	
	Evening maximum PEF[a]			0.0104

COPD-OEQ item	Measure	n	LSMean (SE)	*P* value
	Red zone: <200 LPM	41	2.8 (0.2)	
	Yellow zone: 200-320 LPM	29	2.4 (0.2)	
	Green zone: 320-400 LPM	9	1.7 (0.3)	
OEQ 5. You were satisfied with how quickly you felt your study medication begin to work	**PGIS**			0.7835
	None/mild	27	2.9 (0.2)	
	Moderate	55	2.8 (0.1)	
	Severe/very severe	13	2.8 (0.3)	
	FEV$_1$ improvement			0.0440
	<12%	60	2.7 (0.1)	
	≥12%	36	3.1 (0.2)	
	Morning maximum PEF[a]			0.1919
	Red zone: <200 LPM	42	3.0 (0.2)	
	Yellow zone: 200-320 LPM	23	2.5 (0.2)	
	Green zone: 320-400 LPM	12	2.7 (0.3)	
	Evening maximum PEF[a]			0.0253
	Red zone: <200 LPM	41	3.0 (0.2)	
	Yellow zone: 200-320 LPM	29	2.8 (0.2)	
	Green zone: 320-400 LPM	9	2.0 (0.3)	

[a]Morning and evening PEF starts on Day 2.

COPD, chronic obstructive pulmonary disease; OEQ, Onset of Effect Questionnaire, LSMean, least squares mean; SE, standard error; PGIS, Patient Global Impression of COPD Severity; FEV_1, forced expiratory volume in the first second; PEF, peak expiratory flow; LPM, liters per minute.

Table S3. COPD-OEQ Weekly and Daily – Dichotomized Response Distribution (%) at Baseline, by Medication Class

Characteristic, n (%)	Strongly disagree/somewhat disagree/neither agree nor disagree	Somewhat agree/strongly agree
COPD-OEQ Weekly		
OEQ 1. You could tell your study medication was working		
Non-ICS (LABA/LAMA + LAMA)	18 (50.0)	18 (50.0)
ICS (ICS/LABA + ICS/LABA/LAMA)	14 (21.2)	52 (78.8)
OEQ 2. You could feel your study medication begin to work right away		
Non-ICS (LABA/LAMA + LAMA)	19 (52.8)	17 (47.2)
ICS (ICS/LABA + ICS/LABA/LAMA)	22 (33.3)	44 (66.7)
OEQ 5. You were satisfied with how quickly you felt your study medication begin to work		
Non-ICS (LABA/LAMA + LAMA)	18 (50.0)	18 (50.0)
ICS (ICS/LABA + ICS/LABA/LAMA)	22 (33.3)	44 (66.7)
COPD-OEQ Daily		

OEQ 1. You could tell your study medication was working		
Non-ICS (LABA/LAMA + LAMA)	17 (47.2)	19 (52.8)
ICS (ICS/LABA + ICS/LABA/LAMA)	8 (12.3)	57 (87.7)
OEQ 2. You could feel your study medication begin to work right away		
Non-ICS (LABA/LAMA + LAMA)	22 (61.1)	14 (38.9)
ICS (ICS/LABA + ICS/LABA/LAMA)	17 (26.2)	48 (73.8)
OEQ 5. You were satisfied with how quickly you felt your study medication begin to work		
Non-ICS (LABA/LAMA + LAMA)	20 (55.6)	16 (44.4)
ICS (ICS/LABA + ICS/LABA/LAMA)	18 (27.7)	47 (72.3)

COPD, chronic obstructive pulmonary disease; OEQ, Onset of Effect Questionnaire; ICS, inhaled corticosteroid; LABA, long-acting beta-agonist; LAMA, long-acting muscarinic antagonist.