Sponsor Summation

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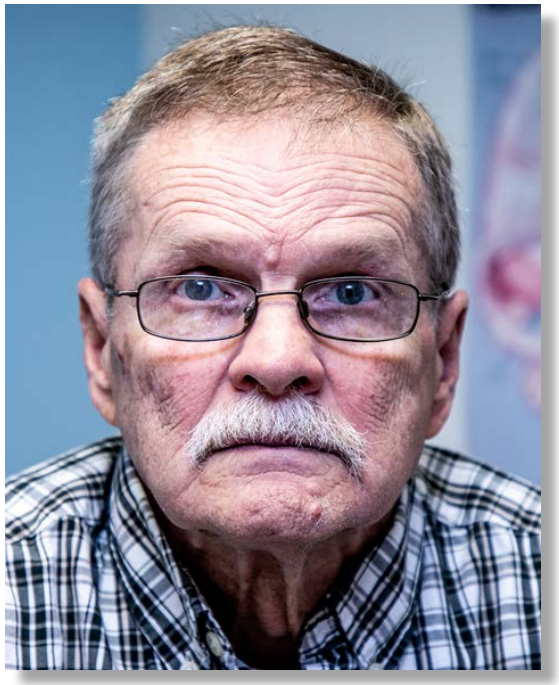
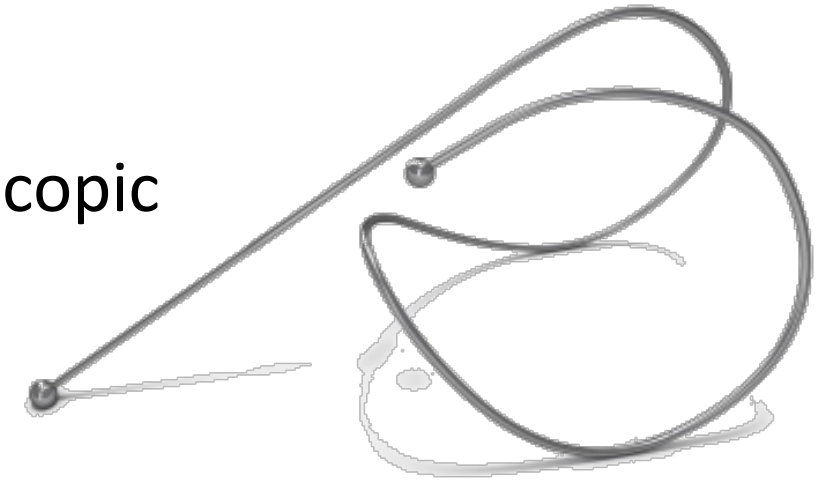
Severe Emphysema Patients With Severe Hyperinflation Have Poor Quality of Life



ELEVAIR™ Endobronchial Coil System Overview

- Designed to treat the specific pathophysiology of emphysema
  - Reduce lung hyperinflation, relieve breathlessness, and improve quality of life
- Device consists of Coils and a Delivery System
  - Coils: nitinol shape-memory implants
  - Delivery System: Minimally invasive, bronchoscopic



Coil

Proposed Indications for Use

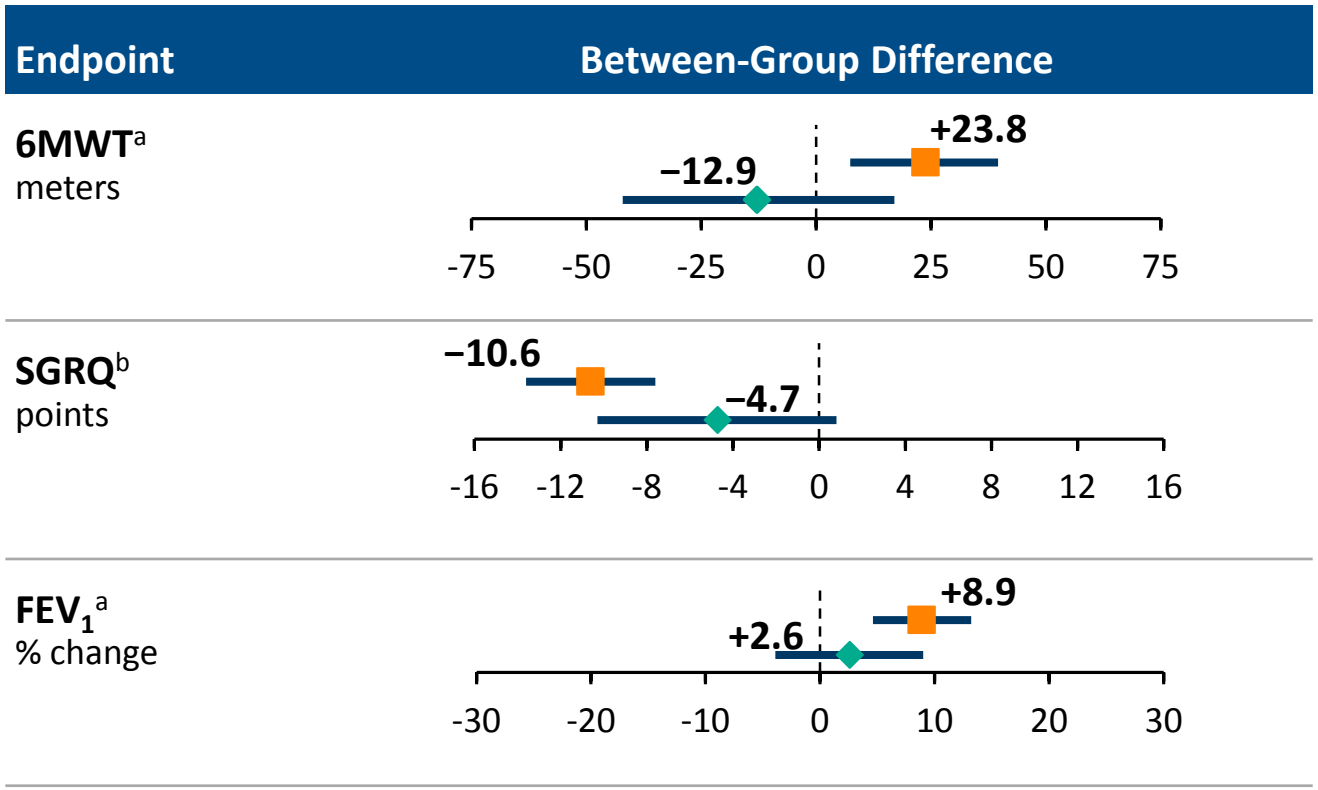
- The ELEVAIR™ Endobronchial Coil System is indicated for bronchoscopic placement of ELEVAIR Coils in patients with severe emphysema (homogeneous and/or heterogeneous) and severe hyperinflation to improve quality of life, lung function, and exercise capacity

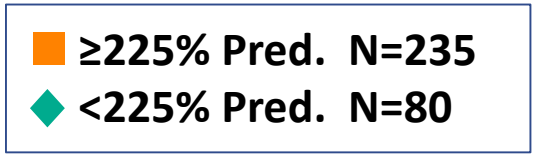
RENEW ITT Baseline Characteristics: Severe and Symptomatic Patient Population

Characteristic[a]	Treatment N=158	Control N=157
Emphysema distribution, % (n)		
Heterogeneous	22.8 (36)	22.9 (36)
Homogeneous	77.2 (122)	77.1 (121)
GOLD status, % (n)		
GOLD 3	24.1 (38)	28.7 (45)
GOLD 4	75.9 (120)	71.3 (112)
FEV_1 % predicted	25.7 ± 6.3	26.3 ± 6.7
RV % predicted	245.9 ± 39.1	244.5 ± 38.7
6MWT, meters	312.0 ± 79.9	302.7 ± 79.3
mMRC dyspnea scale	2.88 ± 0.74	2.84 ± 0.73
SGRQ, points	60.1 ± 12.8	57.4 ± 14.8
DLCO % predicted	34.1 ± 10.5	34.5 ± 10.7
Number of comorbidities	2.6 ± 2.0	2.3 ± 1.8

[a] Mean ±SD, unless otherwise noted.

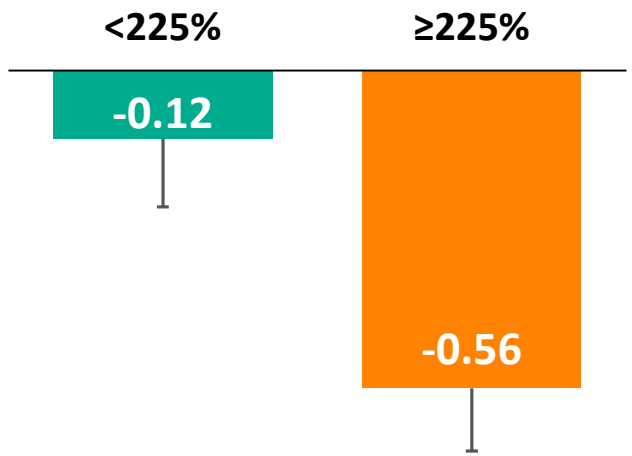
Effectiveness Outcomes are Consistently Greater in Subjects with RV ≥225% Compared to <225%





Exploratory Endpoint

RV change from baseline (liters)

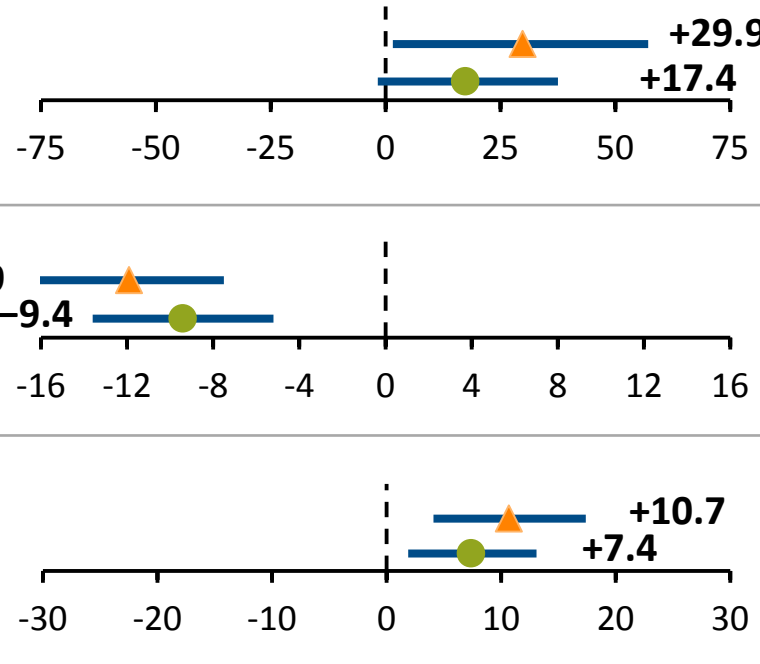


[a] Median difference; [b] Adjusted mean difference.
All endpoints shown above are prespecified.
Not shown: 6MWT Responder Rate (secondary endpoint).

Note: Figure was not provided within the PMA; however, underlying information / analysis was included.

Effectiveness in both US and Outside US Subjects with RV ≥225%

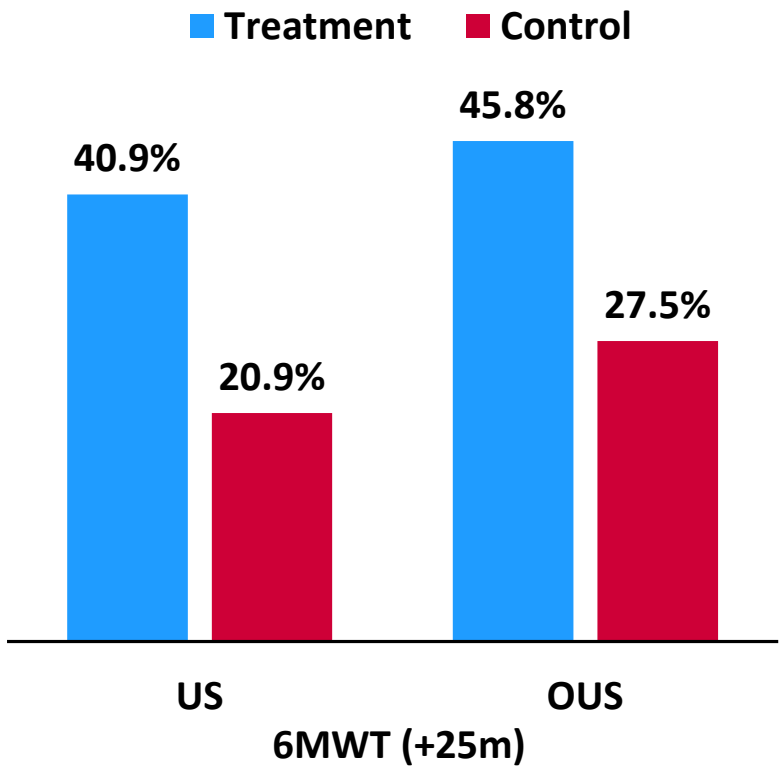
Endpoint	Between-Group Difference
6MWT[a] meters	+29.9, +17.4
SGRQ[b] points	−11.9, −9.4
FEV_1[a] % change	+10.7, +7.4



[a] Median difference; [b] Adjusted mean difference.
All endpoints shown are prespecified.

▲ OUS, RV ≥225% N=107
● US, RV ≥225% N=128

Poolability test:
All p≥0.35



Apparent regional differences in effectiveness were driven by differences in baseline RV by region

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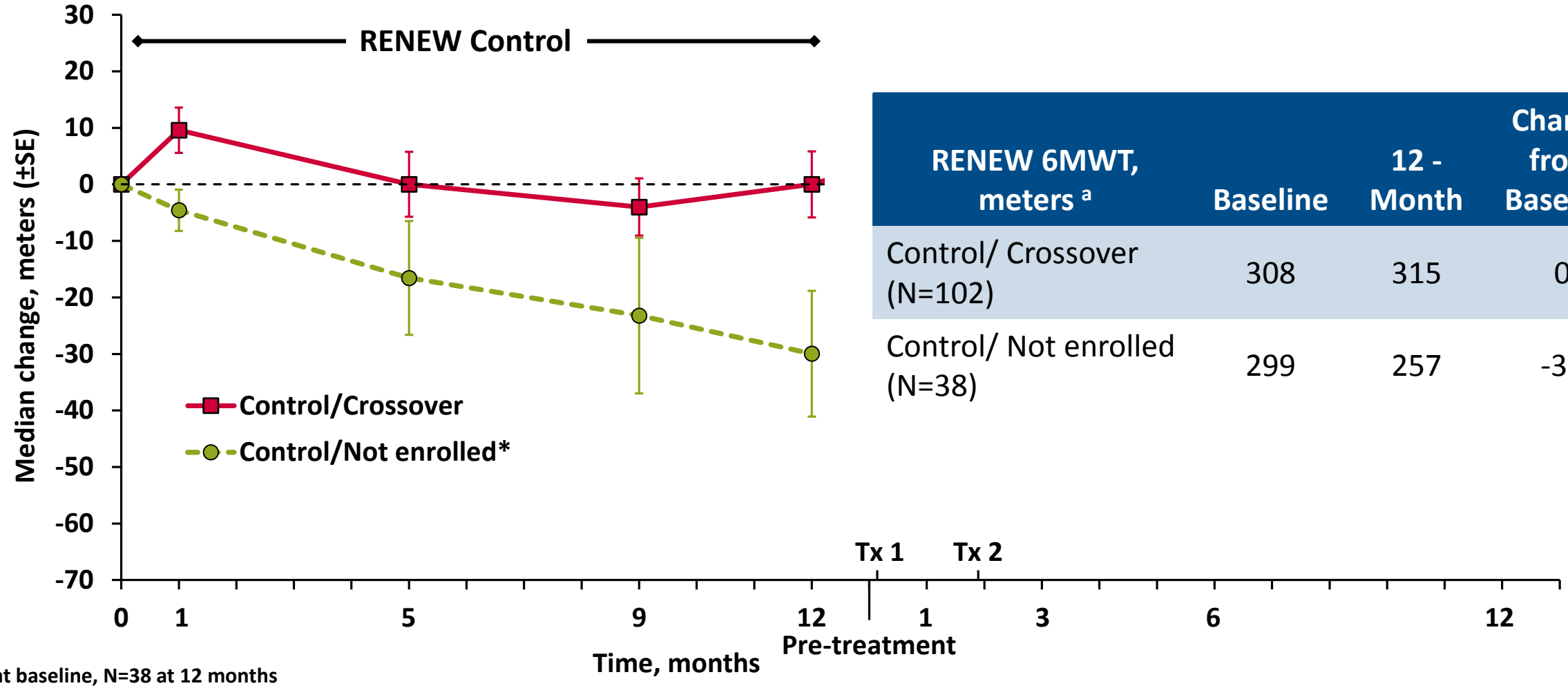
Crossover Subject Selection



RENEW 6MWT, meters [a]	Baseline	12 - Month	Change from Baseline
Control/ Crossover (N=102)	308	315	0
Control/ Not enrolled (N=38)	299	257	-30

*N=55 at baseline, N=38 at 12 months

[a]All values reported as non-adjusted medians based on available data at each visit.

Note: Figure was not provided within the PMA; however, underlying information / analysis was included.

Major Complications (MCs) Through 12 Months

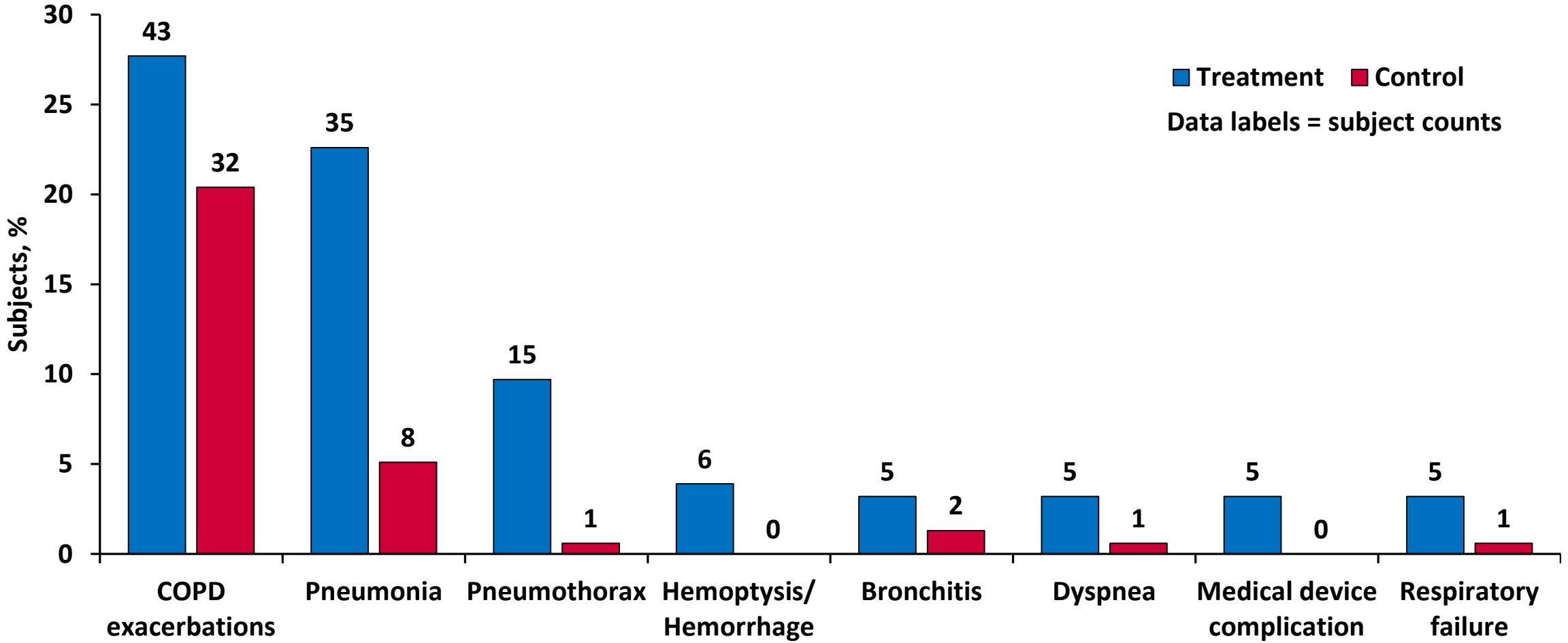
RENEW Randomized

Major complication	Subjects, n (%) Treatment N=155	Subjects, n (%) Control N=157	P-value[a]
Total major complication events (95% CI)[b]	54 (34.8) (27.4, 42.9)	30 (19.1) (13.3, 26.1)	0.0021
Death	10 (6.5)	8 (5.1)	NS
Pneumothorax	1 (0.6)	1 (0.6)	NS
Hemoptysis requiring intervention	2 (1.3)	0	NS
COPD exacerbation	18 (11.6)	13 (8.3)	NS
Lower respiratory infections	29 (18.7)	7 (4.5)	<0.0001
Respiratory failure	6 (3.9)	6 (3.8)	NS
Unanticipated bronchoscopy	0	0	N/A

[a] Nominal p value By Fisher's exact test unadjusted for multiplicity.
[b] By Clopper-Pearson method

Most Frequent Serious Adverse Events Though 12 Months

RENEW Randomized



Pneumonia, terms used: Pneumonia, Pneumonia Bacterial, Pneumonia Staphylococcal, Bronchopulmonary Aspergillosis, Pneumonia Necrotizing, Pneumonia Respiratory Syncytial Virus, Lower Respiratory Tract Infection.

Hemoptysis/Hemorrhage, terms used: Hemoptysis, Post Procedural Hemorrhage, Procedural Hemorrhage, Pulmonary Hemorrhage, Respiratory Tract Hemorrhage.

Note: Figure was not provided within the PMA; however, underlying information / analysis was included.

Post-Market Plan Elements

- Launch based on “Centers of Excellence” model
  - Treatment centers: offer therapy
  - Model treatment centers: offer therapy and host training program
- Comprehensive physician training program
  - Adapted based on post-market plan feedback
- Focused US post-approval study to collect additional safety and effectiveness data
- Ongoing European clinical study program and RENEW to collect long-term safety data
- Ongoing post-market surveillance program

The Study Suggests There is a Group of Patients in the Target Population for Whom the Benefit of a Coil Treatment Likely Outweighs the Risk when Compared to Maximum Medical Therapy

Full Survey Sample

- Benefit > Risks (32%)
- Risks > Benefits (68%)

Survey Sample With RV ≥225%

- Benefit > Risks (51%)
- Risks > Benefits (49%)

Patient preference for the additional risk of pneumonia requiring hospitalization was extrapolated from 15% to 17.5% (full sample) or 17.3% (RV ≥225% predicted).

Note: Figure was not provided within the PMA; however, underlying information / analysis was included.

Benefit – Risk Profile Assessment

Benefits

Meaningful improvement in

- Lung function
- Quality of life
- Exercise capacity

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Risks

Increased risk of

- COPD exacerbation
- Pneumonia
- Pneumothorax
- Bleeding

The ELEVAIR™ System Provides a Meaningful Clinical Tool to Help Severe Emphysema Patients Who Are Seeking Options