

Improvement in Quality of Life in Asthma Patients Switched to Fixed Triple Combination with Beclometasone/Formoterol/Glycopyrronium: 12-Month Results of TriMaximize Study



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TRIMAXIMIZE

BACKGROUND:

- Randomized clinical trials have shown clinical efficacy of extrafine formulation single-inhaler triple therapy consisting of beclometasone dipropionate/formoterol fumarate/glycopyrronium (BDP/FF/G)¹.
- TriMaximize study observes patients who have been switched to BDP/FF/G in a real-world setting over a period of one to three years.

METHODS:

- TriMaximize is a multinational, observational study that follows patients with moderate to severe asthma who have been prescribed BDP/FF/G in medium (MS, 87/5/9 µg) or high strength (HS, 172/5/9 µg). Patients were recruited at 162 sites across eight countries (Germany, United Kingdom, Austria, Denmark, France, Spain, Poland and Italy).
- Health-related quality of life (HRQoL) was assessed by Mini Asthma Quality of Life Questionnaire (Mini AQLQ)². Mini AQLQ is a 15-item questionnaire designed to describe both symptoms severity and asthma-related limitations during the last two-week period (range: 1-7 points). Higher score reflect a better HRQoL. The Minimal clinically important difference (MCID) for Mini AQLQ is 0.5 points.

RESULTS:

Figure 1. Change in Asthma-related impairment of Health-Related Quality of Life from baseline to Month 12, assessed by Mini AQLQ score and stratified by medium or high strength of BDP/FF/G.

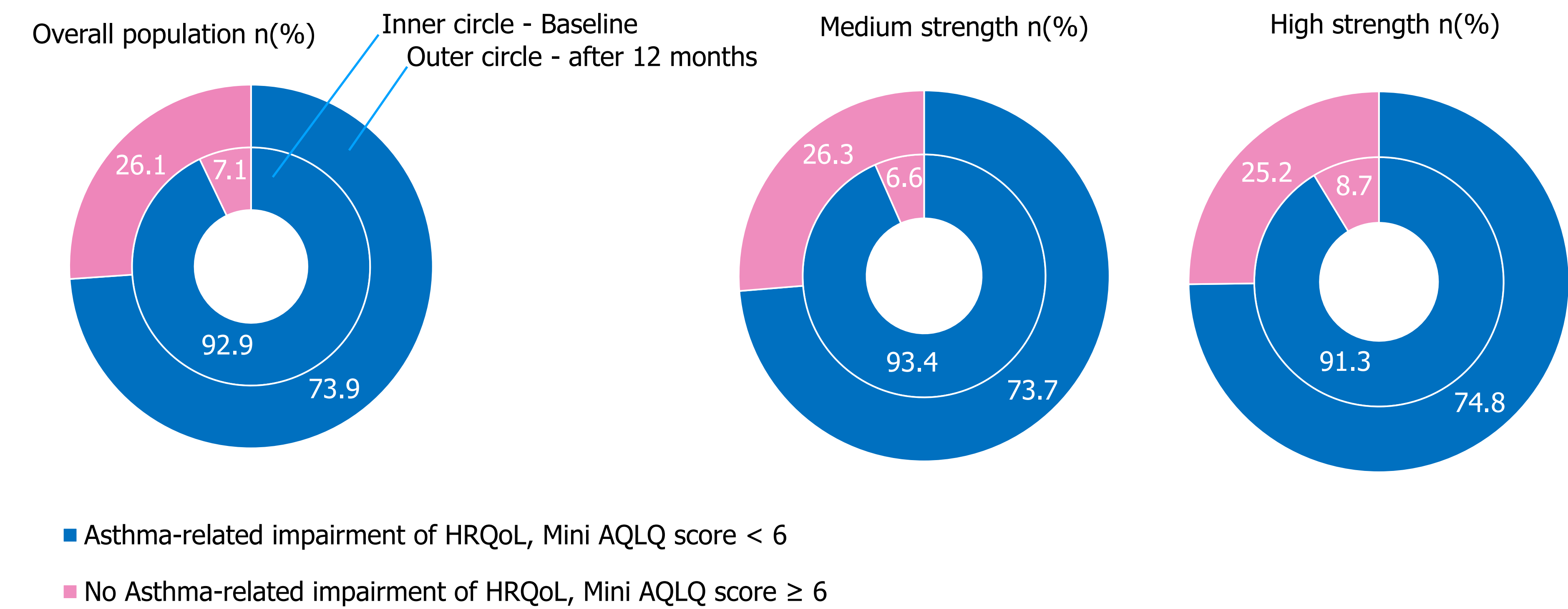


Figure 2. Mean Mini AQLQ score and sub-domains at baseline, and after months 6 and 12, in the overall study population.

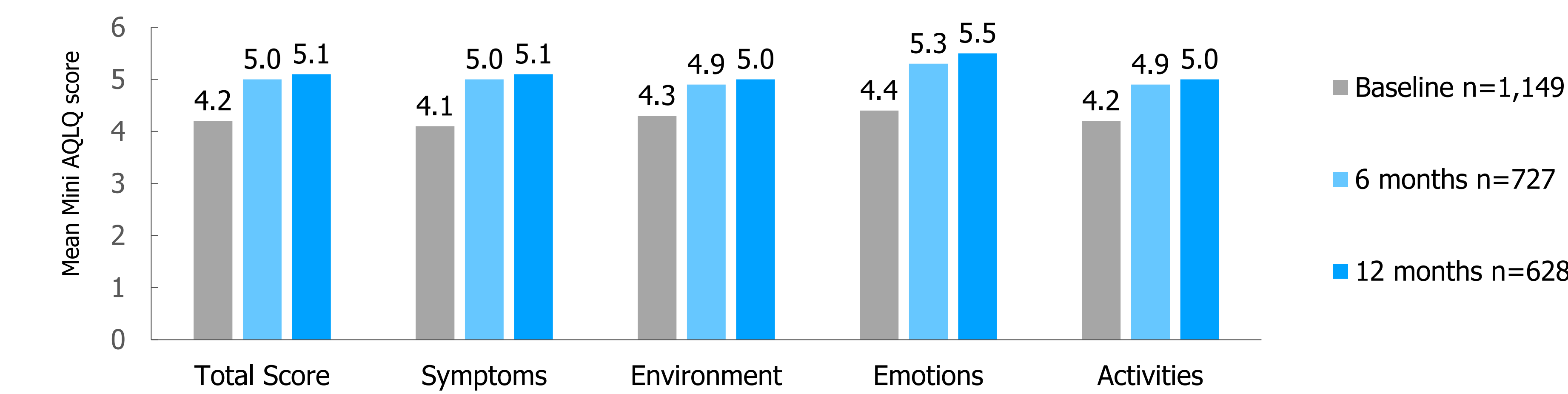


Figure 3. Change in mean Mini AQLQ score from baseline to month 6 and 12, stratified by medium and high strength of BDP/FF/G a) and by prior maintenance treatment b).

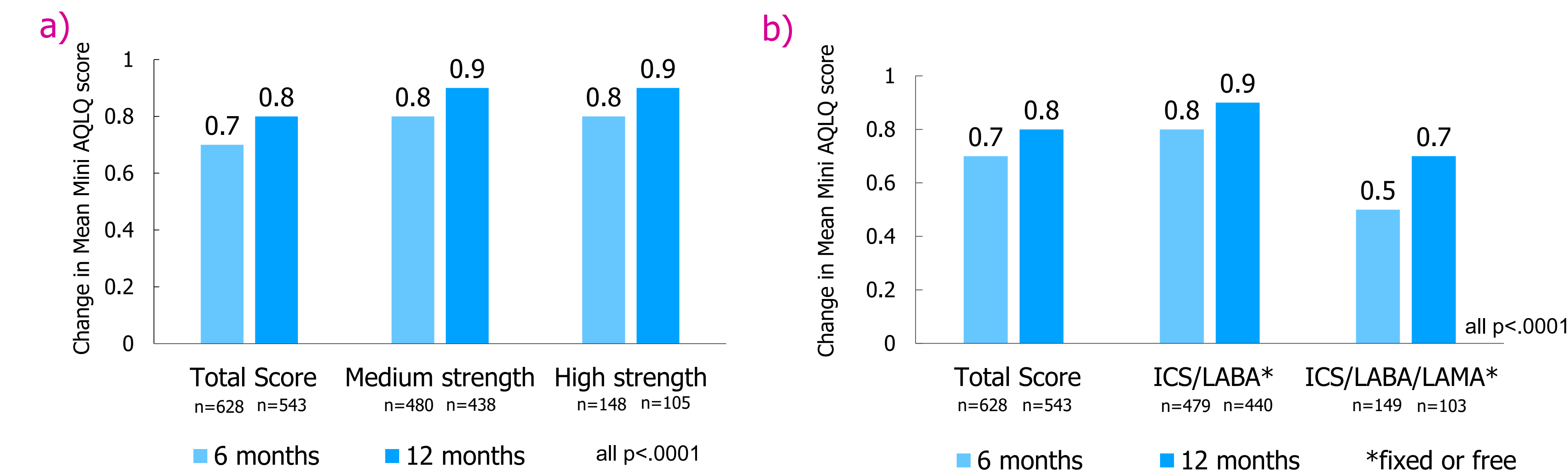


Table 2. Proportion of responders based on the Mini AQLQ score at 12 months, defined by an MCID ≥ 0.5 points, stratified by prior asthma maintenance treatment.

Overall population	
Prior asthma maintenance treatment	Patients with mean ΔMini AQLQ score ≥0.5 (12 months from baseline), n (%)
ICS/LABA* n=440	274 (62.3)
ICS/LABA/LAMA* n=103	60 (58.3)
Overall n=543	334 (61.5)

Medium strength (MS BDP/FF/G)	
Prior asthma maintenance treatment	Patients with mean ΔMini AQLQ score ≥0.5 (12 months from baseline), n (%)
ICS/LABA* n=368	233 (63.3)
ICS/LABA/LAMA* n=70	40 (57.1)
Overall MS n=438	273 (62.3)

High strength (HS BDP/FF/G)	
Prior asthma maintenance treatment	Patients with mean ΔMini AQLQ score ≥0.5 (12 months from baseline), n (%)
ICS/LABA* n=72	41 (56.9)
ICS/LABA/LAMA* n=33	20 (60.6)
Overall HS n=105	61 (58.1)

*fixed or fee

➔ Overall, 61.5 % of patients met or exceeded the MCID of 0.5 points for the Mini AQLQ and were classified as responders.

CONCLUSIONS:

- A significant improvement in the health-related quality of life of asthma patients was observed over a 12-month treatment period with the fixed combination of BDP/FF/G in the overall population and in both dose strengths.
- The therapy with BDP/FF/G offers a promising option for the long-term management of moderate to severe asthma.

Table 1. Baseline characteristics of the patients.

Parameters		Overall population n=1,445	Medium strength (87/5/9 µg) n=1,084	High strength (172/5/9 µg) n=361
Age (years), mean (±SD)		57.9 (15.0)	57.9 (14.8)	56.4 (15.4)
Sex, n (%)	Female	907 (62.8)	685 (63.2)	222 (61.5)
	Male	538 (37.2)	399 (36.8)	139 (38.5)
BMI (kg/m ²), mean (±SD)		28.9 (6.4)	28.8 (6.4)	29.2 (6.5)
Smoking status, n (%)	Never smoker	755 (52.2)	561 (51.8)	194 (53.7)
	Current smoker	259 (17.9)	203 (18.7)	56 (15.5)
	Former smoker	431 (29.8)	320 (29.5)	111 (30.7)
Time since stopped smoking (years)* (±SD)		14.7 (12.4)	14.1 (12.2)	16.5 (13.1)
Time since diagnosis at baseline visit, years (±SD)		15.1 (14.7)	13.6 (13.6)	19.7 (16.8)
Concomitant diseases, n (%)		1161 (85.3)	847 (84.1)	314 (88.7)
	Arterial hypertension	507 (37.8)	392 (39.2)	115 (33.7)
	COPD	298 (22.4)	255 (25.7)	43 (12.8)
Rate of moderate or severe asthma exacerbations in previous year, mean (±SD)		1.8 (1.6)	1.8 (1.5)	2.0 (1.9)
Classification according to GINA criteria, n (%)	GINA Step 4	1079 (76.3)	913 (85.3)	166 (48.3)
	GINA Step 5	335 (23.7)	157 (14.7)	178 (51.7)
Previous treatment	ICS/LABA**	1050 (72.7)	854 (78.8)	196 (54.3)
	ICA/LABA/LAMA**	395 (27.3)	230 (21.2)	165 (45.7)

*restricted to former smokers
**fixed or free

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References:

¹ Virchow J.C. et al., Single inhaler extrafine triple therapy in uncontrolled asthma (TRIMARAN and TRIGGER): two double-blind, parallel-group, randomised, controlled phase 3 trials. The Lancet, 2019. 394(10210): p. 1737-1749.

²Development and validation of the Mini Asthma Quality of Life Questionnaire, EF Juniper,GH Guyatt, FM Cox, PJ Ferrie, DR King European Respiratory Journal 1999 14: 32-38; DOI: 10.1034/j.1399-3003.1999.14a08.x

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