

# Effectiveness of **extrafine single-inhaler triple therapy (efSITT)** on asthma control one year post treatment stratified by patients' smoking status: the **TRIANGLE study**

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## INTRODUCTION:

The efficacy of extrafine single-inhaler triple therapy (efSITT), with beclometasone dipropionate/ formoterol fumarate/ glycopyrronium (BDP/FF/G) in asthma has been assessed in randomized controlled trials, excluding though both current and ex-smokers with a smoking history of  $\geq 10$  pack years<sup>1</sup>. TRIANGLE provides real-world evidence of efSITT's effectiveness in asthma patients in Greece.

## AIMS AND OBJECTIVES:

This 1-year observational study aims to assess therapy pathways and health-related outcomes of BDP/FF/G in moderate-to-severe asthma patients, previously treated with medium dose ICS+LABA or open triple therapy, including patients of all smoking statuses.

## METHODS:

This analysis includes 333 patients who received treatment with BDP/FF/G (87/5/9  $\mu\text{g}$ ) for 1 year. The co-primary objectives are to evaluate asthma control (ACT) and description of treatment pathways. In this interim analysis results were stratified by patients' smoking status.

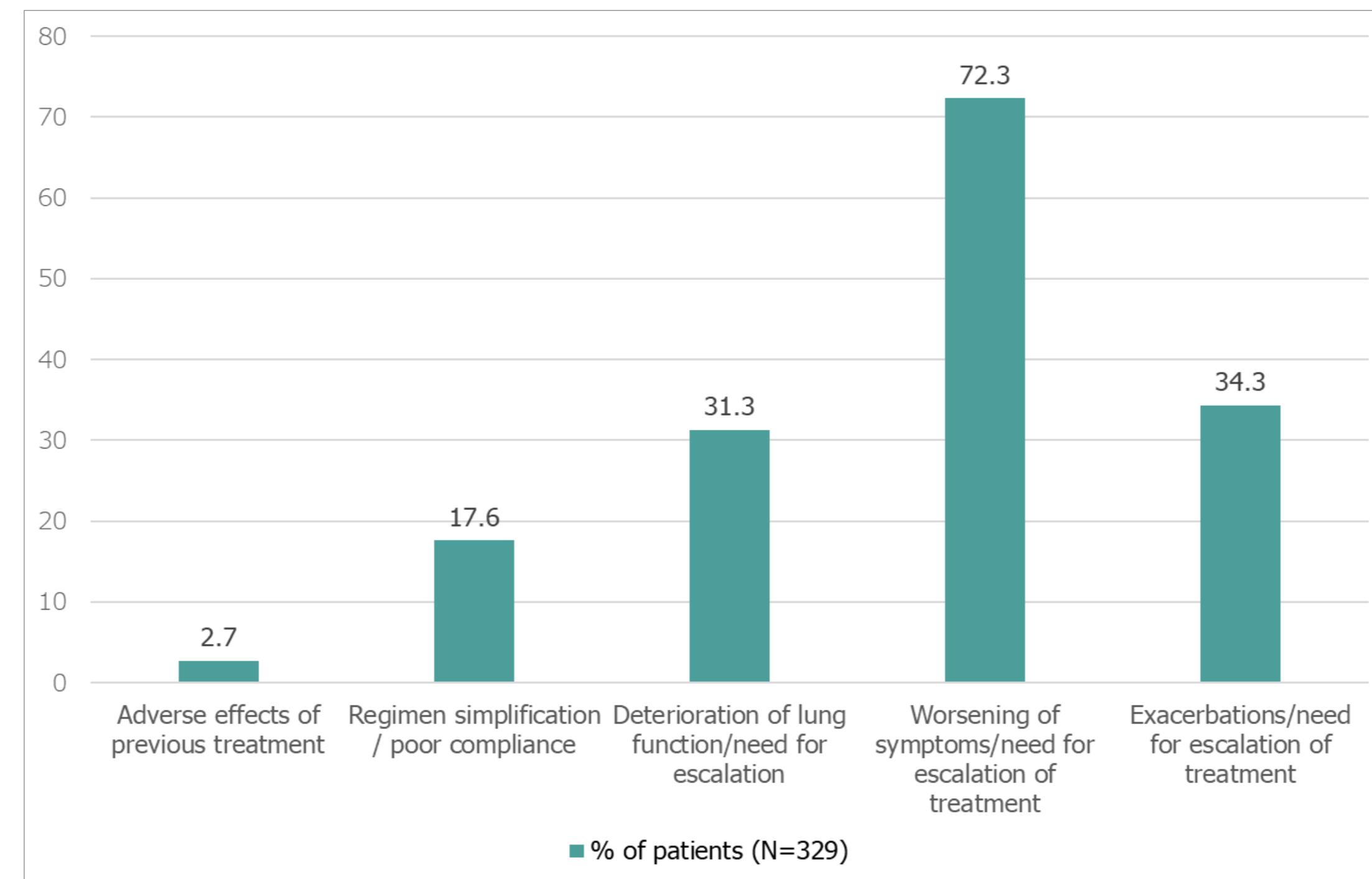
Table 1: Baseline characteristics of patients (N=333)

Characteristics		N	%
Gender	Female	180	54.1
	Male	153	45.9
	Total	333	100.0
Smoking status	Current Smoker	105	31.5
	Former Smoker	97	29.1
	Never a smoker	131	39.3
	Total	333	100
Concomitant COPD diagnosis	No	285	85.6
	Yes	48	14.4
	Total	333	100
Previous asthma treatment	ICS+LABA	271	81.6
	ICS+LABA+LAMA	61	18.4
	Total	333	100
Characteristics		Mean ( $\pm$ SD)	N
BMI (kg/m <sup>2</sup> )	Current Smoker	28.2 (4.9)	105
	Former Smoker	28.6 (5.5)	96
	Never a smoker	28.8 (7.6)	130
	Total	28.6 (6.2)	331
Pack Years	Current Smoker	36.3 (32.9)	105
	Former Smoker	18.9 (17.4)	97
	Never a smoker	0.0	131
	Total	17.0 (25.7)	333
Age (years)	Current Smoker	55 (13.9)	105
	Former Smoker	60.2 (13.2)	97
	Never a smoker	56.1 (15.7)	130
	Total	56.9 (14.6)	332
Asthma duration (years)	Smoker	8.6 (10.3)	105
	Former Smoker	13.4 (13.0)	97
	Never a smoker	12.9 (12.0)	131
	Total	11.7 (11.9)	333

More than 60% of the patients with moderate-severe asthma have been exposed to smoking, while more than 30% were current smokers.

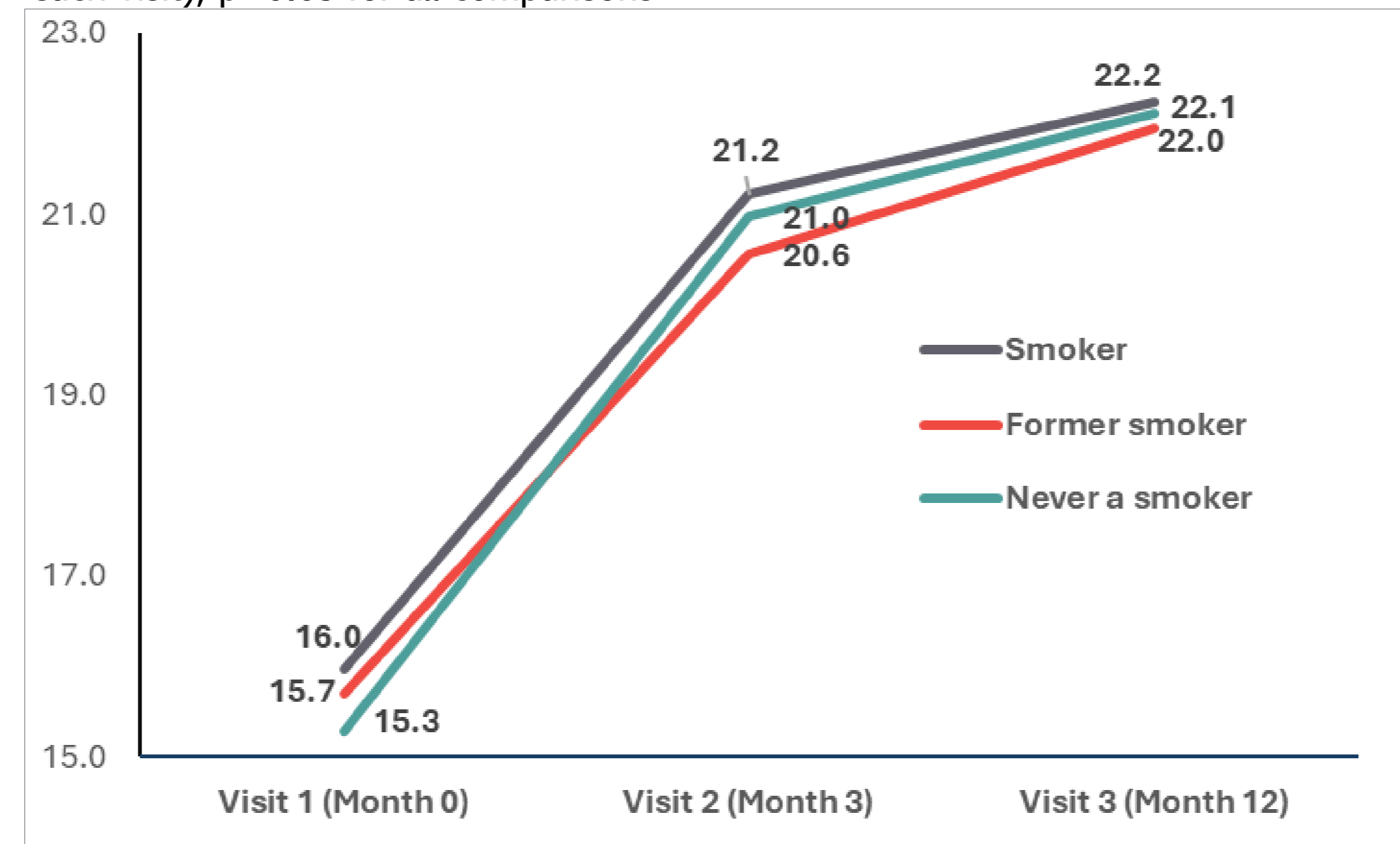
## RESULTS:

Figure 1: Reasons for switching to efSITT BDP/FF/G (87/5/9)



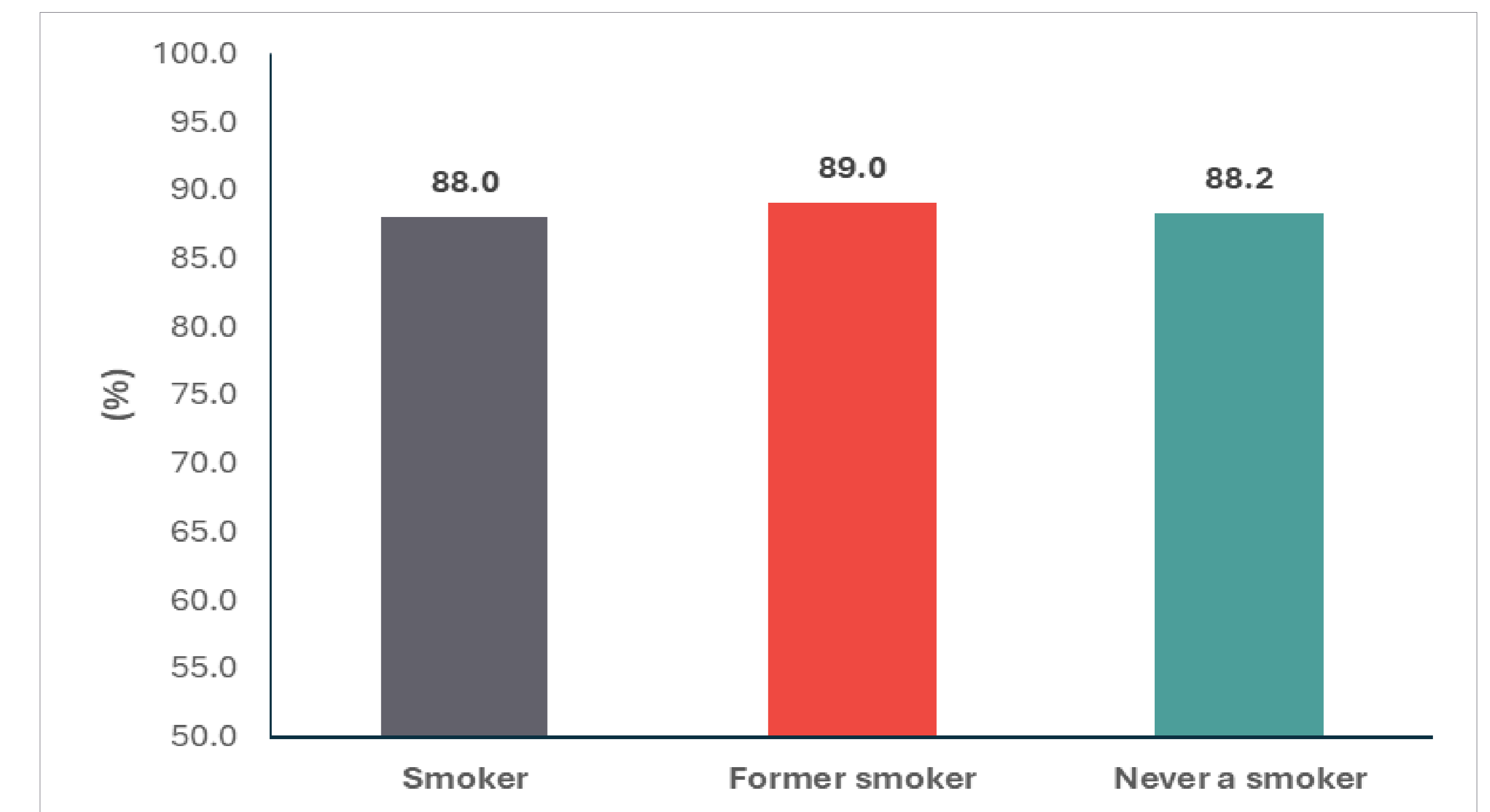
Worsening of symptoms/need for escalation of treatment was the main reason for switching to efSITT (72.3%)

Figure 2: Mean of the total ACT score across the three study visits, by smoking status. The ACT score ranges from 5 (worst status) to 25 (complete control). Base: Number of patients at each visit for whom ACT was recorded (N=331, 331 and 301 respectively for each visit), p<0.05 for all comparisons



After 1 year of treatment, ACT score improved by more than 6 points in all groups (all p<0.05)

Figure 3: Percentage of patients who achieved an ACT improvement of  $\geq 3$  points (3 points is the MCID of ACT<sup>2</sup>) at the final Visit, compared to the score at study entry. Base: Number of patients for whom the parameter was recorded (N= 301).



$\geq 88\%$  of patients in each group achieved the minimum clinically important difference (MCID) in ACT score<sup>2</sup> ( $\geq 3$ -point increase).

## CONCLUSIONS:

Regardless of smoking status, these real-world data show that asthma control can be significantly improved, after switching from medium dose ICS+LABA or open triple therapy to extrafine single-inhaler triple therapy with BDP/FF/G.

### References

- Virchow JC, et al., *Lancet*. 2019 Nov 9;394(10210):1737-1749.
- Schatz M, et al., *J Allergy Clin Immunol*. 2006 Mar;117(3):549-56.

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