ELLIPTA inhaler was rated higher than RESPIMAT in all ease-of-use questionnaire items ($p \leq 0.001$). The incidence of on-treatment AEs was similar in both groups (UMEC/VI, $n=59$ [25%]; TIO/OLO, $n=71$ [31%]).

Conclusions In this first, direct, once-daily LAMA/LABA comparison, a greater likelihood of improvements in lung function was demonstrated with UMEC/VI vs TIO/OLO. The ELLIPTA inhaler was preferred to RESPIMAT. Both LAMA/LABAs were well tolerated.

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Please refer to page A261 for declarations of interest in relation to abstract P275.

Abstract P275 Table 1 Summary of changes from baseline in lung function endpoints and rescue medication use, and trough FEV₁ responder analysis (ITT population)

	N	UMEC/VI	N	TIO/OLO	Difference/OR (95% CI) UMEC/VI vs TIO/OLO
Trough FEV₁, mL					
Week 4	231	189 (13)	224	141 (13)	+48 (25, 71)*
Week 8	225	180 (13)	224	128 (13)	+52 (28, 77)*
Trough FEV₁ responders,[†] n (%)					
Week 4	234	162 (69)	227	116 (51)	OR: 2.09 (1.39, 3.14)*
Week 8	234	154 (66)	229	109 (48)	OR: 2.05 (1.34, 3.14)*
IC, mL					
Week 4	223	164 (17)	215	112 (18)	+52 (16, 88)**
Week 8	212	169 (17)	212	122 (17)	+47 (14, 81)**
Rescue medication use (Weeks 1–8), puffs/day	222	–0.94 (0.08)	217	–0.68 (0.08)	–0.25 (–0.37, –0.14)*

All data are presented as LS mean (SE) change from baseline, unless otherwise stated; * $p < 0.001$; ** $p < 0.01$; [†]Defined as a change from baseline in trough FEV₁ of ≥ 100 mL; CI, confidence interval; FEV₁, forced expiratory volume in 1 s; IC, inspiratory capacity; ITT, intent-to-treat; LS, least squares; OR, odds ratio; SE, standard error; TIO/OLO, tiotropium/olodaterol 5/5 mcg; UMEC/VI, umeclidinium/vilanterol 62.5/25 mcg

P276

CARDIOVASCULAR SAFETY OF EXTRA-FINE SINGLE INHALER TRIPLE COMBINATION OF BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, AND GLYCOPYRRONIUM BROMIDE IN COPD: RESULTS OF SAFETY ANALYSIS FROM THE TRILOGY AND TRINITY STUDIES

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Rationale COPD often co-exists with other chronic diseases that can contribute to patients' health status and prognosis. In particular, patients with COPD are at greater risk of cardiovascular disease compared with age and sex-matched controls.

Methods Two 52 week multi-centre, randomised, double-blind, active-controlled studies recruited patients with symptomatic COPD, severe to very severe airflow limitation, and an exacerbation history. In TRILOGY, patients were randomised (1:1) to an extrafine fixed triple combination of beclometasone

dipropionate, formoterol fumarate, and glycopyrronium bromide (BDP/FF/GB; 100/6/12.5 mcg, two actuations twice daily [BID] via pressurised metered dose inhaler [pMDI]; 'fixed triple') or an extrafine fixed combination of BDP/FF (100/6 mcg, two actuations BID via pMDI; Fostair) (Singh et al. Lancet 2016; 388: 963–73). In TRINITY patients were randomised 2:2:1 to BDP/FF/GB, tiotropium (18 mcg once daily via single-dose dry powder inhaler [SDDPI]), or BDP/FF+tiotropium: free triple (Vestbo et al. Lancet 2017; 389: 1919–29). In this analysis, we evaluated the occurrence of Major Adverse Cardiovascular Events (MACEs). MACEs included acute myocardial infarction, stroke, cardiovascular death, arrhythmias, and heart failure.

Results MACE incidence and rate in the two BDP/FF/GB groups was similar to the BDP/FF and tiotropium groups (Table 1). The majority of reported MACEs were severe in intensity, with a slightly higher percentage of fatal events in the Tiotropium only group. Importantly, in patients with relevant concomitant cardiovascular diseases, the trend was similar to that seen in the overall populations. None of the other subgroup analyses (by age, spacer use and gender) highlighted relevant differences in the safety profiles compared with the overall population.

Conclusions These Results provide further reassurance that the additional clinical benefits of this extrafine fixed triple compared to standard treatment are not associated with a greater impact on the cardiovascular safety in severe to very severe COPD patients, further supporting its positive benefit/risk ratio. Importantly, the presence of concomitant cardiac comorbidities did not influence the rate of cardiovascular events.

Please refer to page A261 for declarations of interest in relation to abstract P276.

Abstract P276 Table 1 Patients (%) with MACE, and MACE rate per 1000 patient years in TRILOGY and TRINITY

	TRILOGY		TRINITY		
	BDP/FF/GB (Fixed Triple) (n=687)	BDP/FF (Fostair [®]) (n=680)	BDP/FF/GB (Fixed Triple) (n=1077)	Tiotropium (n=1076)	BDP/FF +Tiotropium (Free Triple) (n=537)
Treatment-emergent MACEs, n(%)	15 (2.2%)	15 (2.2%)	20 (1.9%)	23 (2.1%)	7 (1.3%)
Acute Myocardial infarction	1 (0.1%)	6 (0.9%)	2 (0.2%)	4 (0.4%)	0
Arrhythmias	3 (0.4%)	2 (0.3%)	1 (0.1%)	1 (0.1%)	1 (0.2%)
Cardiovascular death	3 (0.4%)	3 (0.4%)	8 (0.7%)	6 (0.6%)	2 (0.4%)
Heart failure	6 (0.9%)	3 (0.4%)	0	8 (0.7%)	2 (0.4%)
Stroke	2 (0.3%)	2 (0.3%)	9 (0.8%)	3 (0.3%)	2 (0.4%)
Unknown cause of death	0	0	0	1 (0.1%)	0
Any fatal MACE	4 (0.6%)	5 (0.7%)	10 (0.9%)	12 (1.1%)	2 (0.4%)
MACE rate per 1000 patient years	24.9	25.6	19.5	23.5	13.6

P277

BISOPROLOL BLUNTS DOMICILIARY FEV1 IN COPD PATIENTS TAKING CONCOMITANT DUAL OR TRIPLE INHALER THERAPY

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