

SUPPLEMENTARY DATA

Table S1. Person-Time Summary

	Exubera (N=3848)					Comparator (N=3541)					Total (N=7389)				
	Retrospective PY			Prosp. PY	Total PY	Retrospective PY			Prosp. PY	Total PY	Retrospective PY			Prosp. PY	Total PY
	Total	Orig. Trial	After Trial*			Total	Orig. Trial	After Trial*			Total	Orig. Trial	After Trial*		
Group 1	2171	2171	0	0	2171	2085	2085	0	0	2085	4256	4256	0	0	4256
Group 2	2581	1856	725	0	2581	2444	1782	662	0	2444	5025	3638	1387	0	5025
Group 3	5125	3768	1357	2729	7854	4703	3430	1273	2570	7273	9828	7198	2630	5299	15127
Total	9877	7795	2082	2729	12606	9232	7297	1935	2570	11803 [†]	19109	15092	4017	5299	24409 [†]

* 'After Trial' refers to the portion of retrospective person-time after the original trial to the screening date

[†] Includes one additional PY beyond the addition of retrospective and prospective PY due to rounding

Abbreviations: N = number of patients, PY = person-years, Orig. Trial = original trial person-years, Prosp. PY = prospective follow-up person-years, Group 1 = FUSE patients who could not participate in the prospective follow-up because site did not participate, Group 2 = FUSE patients who did not participate in the prospective follow-up because the patient could not or chose not to participate, Group 3 = FUSE patients who participated in the prospective follow-up

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Table S2. Endpoint Summary (All Patients)

Endpoint	Randomized Group	Reported as Potential Endpoint	Adjudicated*	Adjudication status†			“Highly likely” or “Likely” Events Included in ‘In Study’ Analyses
				“Highly likely” or “Likely”	“Unlikely”	“Insufficient”	
Primary Lung Cancer Mortality	EXU (N=3875)	5	47	6‡	39	2	1
	Comparator (N=3564)	2	51	2	46	3	1
	Total (N= 7439)	7	98	8‡	85	5	2
Incident Primary Lung Cancer	EXU (N=3875)	14	56	12§	2	1	4
	Comparator (N=3564)	4	53	3	1	0	2
	Total (N= 7439)	18	109	15§	3	1	6

* The number of endpoint occurrences adjudicated for likelihood of primary lung cancer mortality or incidence. Includes cases reported as a potential endpoint and cases not reported as a potential endpoint (i.e., only reported as all-cause mortality endpoints) for which adjudication packages were available. Adjudication was possible for 91 (42 EXU, 49 Comparator) of 156 deaths not reported as a lung cancer death.

† For adjudicated mortality endpoints (including those not reported as lung cancer mortality), adjudication status refers to the likelihood that primary lung cancer was the cause of death. For adjudicated incident lung cancer, adjudication status refers to the likelihood that the patient had incident primary lung cancer

‡ Includes one case not reported as a lung cancer mortality that was identified through adjudication of all-cause mortality endpoints

§ Includes one case not reported as a lung cancer diagnosis that was identified through adjudication of all-cause mortality endpoints

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Table S3. Endpoint Summary (Among Former Smokers)

Endpoint	Randomized Group	Reported as Potential Endpoint	Adjudicated*	Adjudicated Status = “Highly likely” or “Likely”†	
				Events Included in ‘Continuous’ Analyses	Events Included in ‘In Study’ Analyses
Primary Lung Cancer Mortality	EXU (N=1681)	4	31	5‡	1
	Comparator (N=1533)	2	26	2	1
	Total (N= 3214)	6	57	7‡	2
Incident Primary Lung Cancer	EXU (N=1681)	13	40	11§	6
	Comparator (N=1533)	3	27	3	2
	Total (N= 3214)	16	67	14§	8

* The number of endpoint occurrences adjudicated for likelihood of primary lung cancer mortality or incidence. Includes cases reported as a potential endpoint and cases not reported as a potential endpoint (i.e., only reported as all-cause mortality endpoints) for which adjudication packages were available. Adjudication was possible for 51 (27 EXU, 24 Comparator) not reported as a lung cancer death.

† For adjudicated mortality endpoints (including those not reported as lung cancer mortality), adjudication status refers to the likelihood that primary lung cancer was the cause of death. For adjudicated incident lung cancer, adjudication status refers to the likelihood that the patient had incident primary lung cancer

‡ Includes one case not reported as a lung cancer mortality that was identified through adjudication of all-cause mortality endpoints

§ Includes one case not reported as a lung cancer diagnosis that was identified through adjudication of all-cause mortality endpoints

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