SUPPLEMENTARY MATERIALS

Supplementary Table 1. Prevalence of adverse events by symptom and globally for Blacks

and Whites*

Adverse Events	Blacks No. (%) n=220	Whites No. (%) n=214	\mathbf{p}^{\dagger}				
				By Symptom [‡] , Weeks 1-16			
				Hostility, aggression, or other change in behavior not normal for	13 (5.9)	13 (6.1)	.94
you							
Fatigue or loss of energy	18 (8.2)	21 (9.8)	.55				
Nausea	34 (15.5)	43 (20.1)	.21				
Trouble sleeping	26 (11.8)	28 (13.1)	.69				
Headaches	20 (9.1)	17 (7.9)	.67				
Abnormal dreams	29 (13.2)	9 (4.2)	<.001				
Gas or flatulence	37 (16.8)	32 (14.9)	.60				
Constipation	26 (11.8)	18 (8.4)	.24				
Dizziness	8 (3.6)	3 (1.4)	.22				
Dry mouth	18 (8.2)	17 (7.9)	.93				
Irritability	24 (10.9)	27 (12.6)	.58				
Global, Weeks 1-16							
Any [§]	210 (95.5)	206 (96.3)	.67				
Serious Adverse Events ¹	1 (0.5)	6 (2.3)	.12				

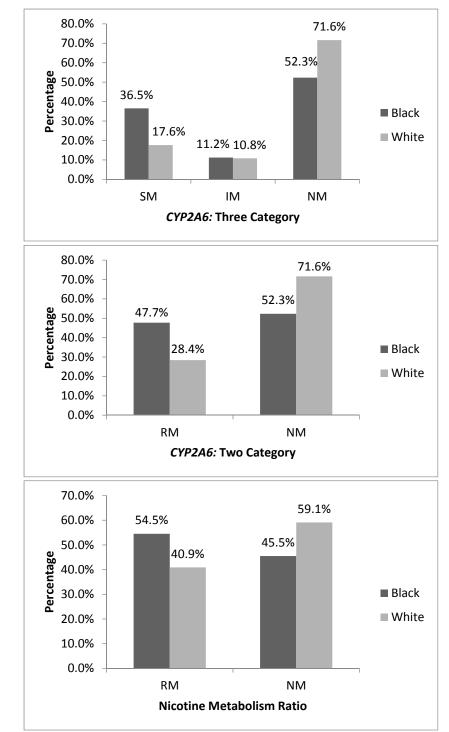
*Varenicline treatment began at Week 0 and continued through Week 12. 4 Blacks and 11 Whites did not return from weeks 1-16 and were excluded from these analyses. All associated

 $^{\dagger}P$ values were calculated using a two-sided Chi-squared test except for dizziness and Serious Adverse Events, which were calculated using a two-sided Fischer's exact test because of the minimal number of events.

[‡]No. and % of participants that reported experiencing each symptom between Weeks 1-16 at a grade 3 (bothers them 'a lot') or 4 (bothers them 'terribly') and that they attributed to varenicline, not another cause.

[§]No. and % of participants that reported any of the above symptom between Weeks 1-16 at a grade 3 (bothers them 'a lot') or 4 (bothers them 'terribly') and that they attributed to varenicline, not another cause.

¹Serious Adverse Events were: Blacks, fluid on the heart (1); Whites, death (1), depressive episode (1), seizure (1), heart attack (1), suicide attempt (1), intestinal blockage (1). All Serious Adverse Events led to hospitalization and/or discontinuation of treatment.



Supplementary Figure 1. Nicotine metabolism by race. Percentage of Blacks and Whites categorized as A. Slow (SM), intermediate (IM), and normal (NM) metabolizers by *CYP2A6*. B. Reduced (RM = IM + SM) and NM metabolizers by *CYP2A6*. C. RM and NM using 3HC/COT cut point of .31 based on prior studies.

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