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Supplementary appendix

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Supplemental appendix

Supplemental text

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***Supplemental Table 1*: Disposition of Subjects**

Disposition	US Study (n=1130)	International Study* (n=1135)
Completed scheduled treatment cycles	582 (51.5)	721 (63.5)
Completed at least 13 cycles	412 (36·4)	529 (46·6)
Completed <13 cycles	170 (15·0)	192 (16·9)
Discontinued prematurely	548 (48.5)	414 (36.5)
Lost to follow-up	138 (12·2)	76 (6·7)
Adverse event	132 (11·7)	146 (12·9)
Withdrew consent	127 (11·2)	64 (5·6)
BMI >29 kg/m^2	88 (7·8)	N/A
Compliance	26 (2·3)	19 (1·7)
Pregnancy	25 (2·2)	29 (2·6)
CVR expulsion	9 (0·8)	24 (2·1)
Eligibility	2 (0·2)	56 (4·9)
Other	1 (0·1)	N/A

*Includes 5 US, 3 Latin American, 3 European, and 1 Australian site

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***Supplemental Table 2*: Demographic and Baseline Characteristics**

Characteristic	US Study (n=1130)	International Study (n=1135)
Age (years), mean±SD	26·6±5·0	26·7±5·2
Age distribution (years), n (%)		
18–19	56 (5·0)	84 (7·4)
20–24	437 (38·7)	405 (35·7)
25–29	376 (33·3)	368 (32·4)
30–35	186 (16·4)	199 (17·5)
36–40	75 (8·6)	79 (7·0)
Body mass index (BMI; kg/m^2), mean±SD	24·1±3·9	23·8±3·5
BMI distribution (kg/m^2)		
value ≤20	131 (11·6)	117 (10·3)
20< value ≤25	589 (52·1)	642 (56·6)
25< value ≤27	162 (14·3)	168 (14·8)
27< value ≤29	128 (11·3)	128 (11·3)
29< value	120 (10·6)	80 (7·0)
Race, n (%)*		
Caucasian	748 (66·3)	985 (86·8)
Black	262 (23·1)	150 (13·2)
Asian	67 (5·9)	35 (3·1)
American Indian or Native Alaskan	12 (1·1)	13 (1·1)
Native Hawaiian or Pacific Islander	10 (0·9)	3 (0·3)
Other/Unknown	76 (6·7)	42 (3·7)
Ethnicity, n (%)		
Hispanic or Latina	149 (13·2)	502 (44·2)
Non-Hispanic or non-Latina	981 (86·8)	633 (55·8)
Marital status, n (%)		
Never married	809 (71·6)	776 (68·4)
Married	232 (20·5)	303 (26·7)
Divorced	62 (5·5)	33 (2·9)
Separated	26 (2·3)	22 (1·9)
Widowed	1 (0·1)	1 (0·1)
Education, n (%)		
College degree or higher	537 (47·5)	411 (36·2)
Some college	453 (40·1)	298 (26·3)
High school diploma/equivalent	115 (10·2)	304 (26·8)
Less than high school	25 (2·2)	122 (10·7)
Desires children after the study, n (%)		
Yes	596 (52·8)	611 (53·8)
No	303 (26·8)	316 (27·8)
Unsure	231 (20·4)	208 (18·3)

Characteristic	US Study (n=1130)	International Study (n=1135)
Smoking, n (%)		
Never smoked	765 (67·7)	825 (72·7)
Former smoker	209 (18·5)	122 (10·7)
Current smoker	155 (13·7)	188 (16·6)
Unknown	1 (0·1)	
Alcohol use history, n (%)		
Never drank	190 (16·8)	394 (34·7)
Former drinker	87 (7·7)	19 (1·7)
Current drinker	853 (75·5)	722 (63·6)

*Multiple races allowed per subject