Supplemental Figure 1.

831 individuals screened

172 excluded (did not meet inclusion criteria)

659 randomized

493 assigned to receive varenicline

486 received treatment as randomized

425 completed 24 weeks of study

493 included in efficacy analysis

486 included in safety analysis

166 assigned to receive placebo

165 received treatment as randomized

141 completed 24 weeks of study

166 included in efficacy analysis

165 included in safety analysis

61 discontinued treatment

9 lost to follow-up

18 declined to participate further

24 adverse events

1 lack of efficacy

9 other

17 of the 61 subjects who discontinued the treatment remained in the study

34 discontinued treatment

10 lost to follow-up

6 declined to participate further

13 adverse events

3 lack of efficacy

2 other

11 of the 34 subjects who discontinued the treatment remained in the study