Prescreened: N = 1561
Screened: N = 1389

Randomized: N = 1380

Excluded: n = 9

Full coverage
Received allocated intervention: n = 696 (100%)
Smoking cessation pharmacotherapy users = 682 (98.0%)

Discontinued study
n = 222 (31.9%)
- Subject died: n = 3
- AEs: n = 6
- Lost to follow-up: n = 160
- No longer willing to participate: n = 42
- Other: n = 11

Completed study: 474 (68.1%)

No coverage
Received allocated intervention: n = 684 (100%)
Smoking cessation pharmacotherapy users = 435 (63.6%)

Discontinued study
n = 267 (39.0%)
- Subject died: n = 5
- AEs: n = 0
- Lost to follow-up: n = 146
- No longer willing to participate: n = 104
- Other: n = 12

Completed study: 417 (61.0%)

*One centre was terminated due to GCP compliance issues. The intent-to-treat (ITT) analysis set was defined as all randomized subjects; all 17 subjects randomized (8 full coverage; 9 no coverage) at this centre were included in the analysis. The same statistical analysis plan was applied for these subjects as defined for Handling of Dropouts or Missing Data (for example: subjects with missing responses to interview questions on whether they had smoked or used any nicotine-containing product in the last 7 days, or missing urine cotinine values were imputed as smokers; in addition, subjects who could not be contacted or were lost to follow-up were considered smokers). In order to assess the impact this may have on the analysis of the primary and key secondary smoking cessation endpoints, additional analyses excluding these subjects were performed.*