

1. Subject Disposition, Visit Attendance, Protocol Violations

11-1. Patient Disposition

Screened Population

| Statistics | Not randomized (N=x) | Placebo (N=x) | GWP42003-P (N=xx) | Total (N=xx) |
|--|-------------------------|------------------|----------------------|-----------------|
| | n (%) | n (%) | n (%) | n (%) |
| Screened Subjects | x (100.0) | x (100.0) | xx (100.0) | xx (100.0) |
| Screen Failure | x (100.0) | | | x (xx.x) |
| Withdrew Consent | x (xx.x) | | | x (xx.x) |
| ... | | | | |
| Randomized | | x (100.0) | xx (100.0) | xx (xx.x) |
| Randomized and Treated Subjects | | x (xx.x) | xx (xx.x) | xx (xx.x) |
| Completed the DB Period | | x (xx.x) | xx (xx.x) | xx (xx.x) |
| Continued in OLE period | | | | |
| Continued to the Taper period | | x (xx.x) | xx (xx.x) | xx (xx.x) |
| Did not continue in OLE or Taper | | | | |
| Reason 1 | | | | |
| ... | | | | |
| Did Not Complete the DB Period | | x (xx.x) | xx (xx.x) | xx (xx.x) |
| Patient/legal representative withdrew consent to participate | | x (xx.x) | xx (xx.x) | xx (xx.x) |
| ... | | x (xx.x) | xx (xx.x) | xx (xx.x) |

Source: Listing 1.1

Percentages are generally based on the number of screened patients except for DB Period status for which percentages are based on randomized patients.

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Repeat this table on the safety and the PK populations.