STANDARD Table

T-VS02: Analysis of Mean (Vital Signs)

VERSION 2.0

| TABLE 14.3\_\_x.x  Analysis of Mean Change from Baseline for Selected Vital Signs  (Analysis Population) | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |
| Variable (unit) |  | | | Within Group  ---- Change from Baseline --- | | | Between Groups Difference  ------- Compared to Control ------- | | |
| Time point  Treatment | N | Baseline  Mean | Visit  Mean | LS  Mean | [95% CI] | SE | LS Mean | [95% CI] | SE |
|  |  |  |  |  |  |  |  |  |  |
| Parameter (standard unit) |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
| Baseline |  |  |  |  |  |  |  |  |  |
| Test Treatment Arm 1 | x |  | x.x |  |  |  |  |  |  |
| Test Treatment Arm 2 | x |  | x.x |  |  |  | x.x | (x.xx, x.xx) | x.xx |
| Test Treatment Arm ... | x |  | x.x |  |  |  | x.x | (x.xx, x.xx) | x.xx |
|  |  |  |  |  |  |  |  |  |  |
| Time point 1 |  |  |  |  |  |  |  |  |  |
| Test Treatment Arm 1 | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx |  |  |  |
| Test Treatment Arm 2 | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx | x.x | (x.xx, x.xx) | x.xx |
| Test Treatment Arm ... | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx | x.x | (x.xx, x.xx) | x.xx |
|  |  |  |  |  |  |  |  |  |  |
| Time point 2 |  |  |  |  |  |  |  |  |  |
| Test Treatment Arm 1 | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx |  |  |  |
| Test Treatment Arm 2 | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx | x.x | (x.xx, x.xx) | x.xx |
| Test Treatment Arm ... | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx | x.x | (x.xx, x.xx) | x.xx |
|  |  |  |  |  |  |  |  |  |  |
| Time point ... |  |  |  |  |  |  |  |  |  |
| Test Treatment Arm 1 | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx |  |  |  |
| Test Treatment Arm 2 | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx | x.x | (x.xx, x.xx) | x.xx |
| Test Treatment Arm ... | x | x.x | x.x | x.x | (x.xx, x.xx) | x.xx | x.x | (x.xx, x.xx) | x.xx |
|  |  |  |  |  |  |  |  |  |  |
| Note: Baseline means include subjects with non-missing baseline and at least one post-baseline value. | | | | | | | | | |

CHG

# Study-Specific Text (to be supplied by Statistician unless otherwise noted)

Analysis Population

Safety Analysis Set

Safety Population

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Treatment Groups

Test Treatment Arm 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Test Treatment Arm … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reference Treatment

Control \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Control … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Time Points

Time point 1

Time point 2

Time point …

Parameter (standard unit): Obtain from data

# Optional Columns and Rows

Comparison to Control (CHG)

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | * Changed the “comparison to control” as optional to accommodate studies without any control * Updated Analysis Population options for consistency across all tables * Updated Test Drug to Test Treatment as referenced in eCRF standard |  |