STANDARD Table

T-VS01: Vital Signs Summary

VERSION 2.0

| TABLE 14.3\_\_x.x  Vital Signs  (Analysis Population) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Variable (unit)  Time point  Treatment | N | Mean | SD | Median | Min | Max |
|  |  |  |  |  |  |  |
| Parameter (standard unit) |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Baseline |  |  |  |  |  |  |
| Test Treatment Arm 1 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm 2 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm ... | x | x.x | x.xx | x.x | x | x |
|  |  |  |  |  |  |  |
| Time point 1 |  |  |  |  |  |  |
| Test Treatment Arm 1 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm 2 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm ... | x | x.x | x.xx | x.x | x | x |
|  |  |  |  |  |  |  |
| Time point 2 |  |  |  |  |  |  |
| Test Treatment Arm 1 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm 2 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm ... | x | x.x | x.xx | x.x | x | x |
|  |  |  |  |  |  |  |
| Time point 3 |  |  |  |  |  |  |
| Test Treatment Arm 1 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm 2 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm ... | x | x.x | x.xx | x.x | x | x |
|  |  |  |  |  |  |  |
| Time point ... |  |  |  |  |  |  |
| Test Treatment Arm 1 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm 2 | x | x.x | x.xx | x.x | x | x |
| Test Treatment Arm ... | x | x.x | x.xx | x.x | x | X |
|  |  |  |  |  |  |  |

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

Analysis Population

Safety Analysis Set

Safety Population

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

Treatment Groups

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

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

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

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

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

Parameter (standard unit): Obtain from data

Time Points

Baseline

Time point 1

Time point 2

Time point 3

Time point …

# Optional Columns and Rows

* Not applicable

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | Updated Analysis Population options for consistency across all tables  Updated Test Drug to Test Treatment as referenced in eCRF standard |  |