STANDARD Table

T-VS04: Listing of Subjects Meeting Criteria for Potentially Clinically Significant Vital Signs

VERSION 2.0

| TABLE 14.3\_\_x.x  Listing of Subjects Meeting Criteria for Potentially Clinically Significant Vital Signs  (Analysis Population) | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Variable (unit)  Treatment  Investigator | Subject  Number | Age/  Sex | Epoch  Name | RX  Day+ | Value | Criteria |
|  | | | | | | |
| Parameter (standard unit) |  |  |  |  |  |  |
|  | | | | | | |
| Test Treatment Arm 1 |  |  |  |  |  |  |
|  | | | | | | |
| Investigator name 1 (site number 1) | 44820 | 62M | PRE | -23 | 138 |  |
|  |  |  | DB | 1 BL | 134 |  |
|  |  |  |  | 15 | 162 | >=160 and >=20 increase |
|  |  |  |  | 29 | 145 |  |
|  |  |  |  | 57 | 134 |  |
|  |  |  | OL | 85 | 157 |  |
|  | | | | | | |
| Investigator name 2 (site number 2) | 50820 | 58M | PRE | -19 | 151 |  |
|  |  |  | DB | 1 BL | 150 |  |
|  |  |  |  | 15 | 167 |  |
|  |  |  |  | 29 | 185 | >=160 and >=20 increase |
|  |  |  |  | 57 | 180 | >=160 and >=20 increase |
|  |  |  | OL | 85 | 160 |  |
|  | | | | | | |
| Investigator name ... (site number ...) | 61928# | 68F | PRE | -10 | 142 |  |
|  |  |  | DB | 1 BL | 122 |  |
|  |  |  |  | 18 | 142 |  |
|  |  |  |  | 28 | 160 | >=160 and >=20 increase |
|  |  |  |  | 54 | 142 |  |
|  |  |  | POST | 83 (7) | 136 |  |
|  | | | | | | |
| + Numbers in parentheses indicate the number of days after the last dose of study Treatment. BL=Baseline.  # Subject prematurely discontinued. | | | | | | |

**F2**

# 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

Sort order for table

Parameter, Treatment, Investigator, Subject ID

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

Investigator name (site number): Obtain from data

Subject number, Age/Sex, Epoch name, RX Day, and Value: Obtain from data. Actual examples shown.

Criteria for potential clinical significance: Obtain from SAP. Actual examples shown.

# Optional Columns and Rows

Include footnote and symbol within table if at least one subject premature discontinued (F2)

# 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 |  |