STANDARD Table

T-LB03: Shift from Baseline to Post-Baseline Based on normal range for lab categoRY

VERSION 2.0

| TABLE 14.3\_\_x.x  Shift from Baseline to Post-Baseline Based on Normal Range for Lab Category  (Analysis Population) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | Baseline High or Normal to  -------------- Post-Baseline Low --------------- | | | Baseline Low or Normal to  -------------- Post-Baseline High --------------- | | |
|  | | ------- Test Treatment ------- | |  | ------- Test Treatment ------- | |
| Variable | Control  (N=x)  n/N\_OBS (%) | Arm 1  (N=x)  n/N\_OBS (%) | Arm 2  (N=x)  n/N\_OBS (%) | Control  (N=x)  n/N\_OBS (%) | Arm 1  (N=x)  n/N\_OBS (%) | Arm 2  (N=x)  n/N\_OBS (%) |
|  |  |  |  |  |  |  |
| Lab test 1 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Lab test 2 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Lab test 3 | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
| Lab test ... | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) | x/x (x.x) |
|  |  |  |  |  |  |  |
| Note: The denominator, N\_OBS, is the number of subjects for the specific variable (row) with a post-baseline value and a baseline  value with the specified evaluation of the normal range. | | | | | | |

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

Lab Category

Chemistry

Hematology

Urinalysis

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

Analysis Population

Safety Analysis Set

Safety Population

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

Treatment Groups

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

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

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

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

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

Lab test: Obtain from data

# 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 the title to Shift from Baseline to Post-Baseline Based on Normal Range for Lab Category * Updated Analysis Population options for consistency across all tables * Updated Test Drug to Test Treatment as referenced in eCRF standard |  |