STANDARD Table

T-LB05: Shift from Baseline to Worst Post-Baseline by each CTC Grade

VERSION 2.0

| TABLE 14.3\_\_x.x  Shift from Baseline to Worst Post-Baseline for Lab Category by Each CTC Grade  (Analysis Population) | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | ------------------------------------ Worst Post-Baseline Grade ----------------------------------- | | | | | |
| Variable (unit)  Treatment  Baseline category | Grade 0  n (%) | Grade 1  n (%) | Grade 2  n (%) | Grade 3  n (%) | Grade 4  n (%) | Missing  n |
|  |  |  |  |  |  |  |
| Lab test (standard unit) - Direction |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Control (N=x) |  |  |  |  |  |  |
| Grade 0 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 4 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Missing | x | x | x | x | x | x |
|  |  |  |  |  |  |  |
| Test Treatment Arm 1 (N=x) |  |  |  |  |  |  |
| Grade 0 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 4 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Missing | x | x | x | x | x | x |
|  |  |  |  |  |  |  |
| Test Treatment Arm ... (N=x) |  |  |  |  |  |  |
| Grade 0 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Grade 4 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x |
| Missing | x | x | x | x | x | x |
|  |  |  |  |  |  |  |
| Note: Percentages calculated on non-missing values in each treatment group.  NCI Common Terminology Criteria version x.x (publish date MON DD, YYYY).  Grade 0 is defined as a value within the normal range or outside the reference range but opposite the direction of concern.  (i.e., low values when the criteria are high and vice versa). | | | | | | |

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

Analysis Population

Safety Analysis Set

Safety Population

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

Lab Category

Chemistry

Hematology

Urinalysis

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

Treatment Groups

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

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

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

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

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

Lab test (standard unit): Obtain from data

Direction: Will be “Low”, “High”, or null, depending on CTC criteria for the specific lab test

NCI Common Terminology Criteria version and date: Obtain from SAP

# 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 |  |