STANDARD Table

T-DM02: Baseline Disease Characteristics

VERSION 3.0

| TABLE 14.1\_\_x.x  **T1**  **T2**  Baseline Disease Characteristics  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | ---------------- Test Treatment ---------------- | | |  |
|  | Control  (N=x) | Arm 1  (N=x) | Arm 2  (N=x) | Total  (N=x) | Total  (N=x) |
|  |  |  |  |  |  |
| Disease duration (year) |  |  |  |  |  |
| n | x | x | x | x | x |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x.x | x.x | x.x | x.x | x.x |
| Min, Max | x, x | x, x | x, x | x, x | x, x |
|  |  |  |  |  |  |
| Disease duration (year) – n (%) |  |  |  |  |  |
| <5 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| >=5 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | x | x | x | x |
|  |  |  |  |  |  |
| Continuous Variable 1(unit) |  |  |  |  |  |
| n | x | x | x | x | x |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) |
| Median | x.x | x.x | x.x | x.x | x.x |
| Min, Max | x, x | x, x | x, x | x, x | x, x |
|  |  |  |  |  |  |
| Continuous Variable 1(unit)– n (%) |  |  |  |  |  |
| <xx | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| >=xx and <xx | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| >=xx | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| … | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Missing | x | x | x | x | x |
|  |  |  |  |  |  |
| … |  |  |  |  |  |
|  |  |  |  |  |  |
| Categorical Variable 1 – n (%) |  |  |  |  |  |
| Level 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Level 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) | x (x.x) | x (x.x) |
| Missing | x | x | x | x | x |
|  |  |  |  |  |  |
| … |  |  |  |  |  |
|  |  |  |  |  |  |
| Note: Percentages calculated on non-missing values.  Disease specific footnotes. | | | | | |

**CAT1**

**CAT2**

**…**

**CON1C**

**CON2C**

**…**

**CON1N**

**CON2N**

**…**

**DURN**

**DURC**

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

Analysis Population

Full Analysis Set

Intent to Treat Population

Safety Analysis Set

Safety Population

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

Treatment Groups

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

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

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

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

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

Disease specific footnotes

#: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

$: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

@: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

… \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Optional Columns and Rows

Total (T1)

Active Total (T2)

Continuous Disease Duration (year) (DURN)

Categorical Disease Duration (year) (DURC)

<5 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

>=5 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Continuous Variable 1 (unit) (CON1N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Continuous Variable 1 (unit) (CON1C) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

<xx \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

>=xx and <xx \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

>=xx \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

…\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Continuous Variable 1 (unit) (CON2N) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Continuous Variable 1 (unit) (CON2C) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐ <xx \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐ >=xx and <xx \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐ >=xx \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

☐ …\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

…

Categorical Variable 1 (CAT1) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Level 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Level 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

… \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Categorical Variable 2 (CAT2) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Level 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Level 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

… \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

…

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | * Change the title from ‘Disease Characteristics’ to ‘Disease Duration’ * Updated Analysis Population options for consistency across all tables * Updated Test Drug to Test Treatment as referenced in eCRF standard |  |
| 3.0 | * Change the title from ‘Disease Duration’ to ‘Baseline Disease Characteristics’ * Put ‘Disease duration (year)’ as an optional row (DURN) and change the optional row ‘DUR’ to ‘DURC’ * Add optional rows for baseline disease characteristics |  |