STANDARD Table

T-TC01: Treatment Compliance

VERSION 2.0

| TABLE 14.1\_\_x.x  **T2**  Treatment Compliance  (Safety Analysis Set) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | -------------------- Test Treatment -------------------- | | | |
| Treatment compliance (%)  Planned time period | Control  (N=x) | Arm 1  (N=x) | Arm 2  (N=x) | Total  (N=x) | |
|  |  |  |  |  | |
| Overall |  |  |  |  | |
| n | x | x | x | x | |
| Mean (SD) | 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 | |
| Min, Max | x, x | x, x | x, x | x, x | |
| Q1, Q3 | x, x | x, x | x, x | x, x | |
|  |  |  |  |  | |
| Planned time period 1 |  |  |  |  | |
| n | x | x | x | x | |
| Mean (SD) | 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 | |
| Min, Max | x, x | x, x | x, x | x, x | |
| Q1, Q3 | x, x | x, x | x, x | x, x | |
|  |  |  |  |  | |
| Planned time period ... |  |  |  |  | |
| n | x | x | x | x | |
| Mean (SD) | 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 | |
| Min, Max | x, x | x, x | x, x | x, x | |
| Q1, Q3 | x, x | x, x | x, x | x, x | |
|  |  |  |  |  | |
| Note: Compliance is defined as the amount of treatment taken divided by the amount of treatment planned during the subject's  Participation in the time period. | | | | |

**PRD**

# 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 … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Optional Columns and Rows

Active Total (T2)

Planned time period (PRD)

Planned time period 1

Planned time period …

# 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 |  |