STANDARD Table

T-PD01: Protocol Deviations

VERSION 3.0

**Crit1**

**Crit2**

| TABLE 14.1\_\_x.x  Protocol Deviations  **T1**  **T2**  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | ----------------- Test Treatment ---------------- | | |  |
| Category | Control  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Total  (N=x)  n (%) | Total  (N=x)  n (%) |
|  |  |  |  |  |  |
| Subjects with at least one protocol deviation | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Subjects who entered the study even though they did not satisfy the entry criteria | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Inclusion criteria not met | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Criterion number 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Criterion number 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Criterion number ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Exclusion criteria met | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Criterion number 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Criterion number 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Criterion number ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Eligibility criteria not met |  |  |  |  |  |
| Criterion number 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Criterion number 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Criterion number ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Subjects who developed withdrawal criteria during the study but were not withdrawn | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Subjects who received the wrong treatment or incorrect dose | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Subjects who received an excluded concomitant treatment | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Note: Includes important protocol deviation categories as suggested in the ICH E3 Guideline.  Subjects are counted only once in each category for which they had a deviation. | | | | | |

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

Inclusion/Exclusion or Eligibility Criterion Number: Obtain from data

# Optional Columns and Rows

All Total (T1)

Active Total (T2)

Inclusion/Exclusion Criterion Number (Crit1)

Eligibility Criterion Number (Crit2)

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | * Combined ‘Inclusion criteria not met’ and ‘Exclusion criteria met’ into ‘Eligibility criteria not met’ based on standard protocol update * Updated Analysis Population options for consistency across all tables * Updated Test Drug to Test Treatment as referenced in eCRF standard |  |
| 3.0 | * Rename option ‘Crit’ to ‘Crit2’ * Add option ‘Crit1’ to separate ‘Inclusion criteria not met’ and ‘Exclusion criteria met’ based on standard protocol update * Removed n (%) from ‘Eligibility criteria not met’ as the n (%) are the same as ‘Subjects who entered the study even though they did not satisfy the entry criteria’ |  |