STANDARD Table

T-DS03: Reason for Study Treatment Discontinuation

VERSION 3.0

| TABLE 14.1\_\_x.x  Reason for Study Treatment Discontinuation  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | ----------------- Test Treatment ----------------- | | |  |
| Discontinuation due to | Control  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Total  (N=x)  n (%) | Total  (N=x)  n (%) |
|  |  |  |  |  |  |
| All reasons$ | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason 4 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason … | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Primary reason | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason 4 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reason … | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| $ Subjects who discontinued study treatment are counted under each reason given for discontinuation, therefore, the sum of the counts given for the reasons may be greater than the overall number of discontinuations. | | | | | |

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

Reasons for Discontinuation: Obtain from data

# Optional Columns and Rows

All Total (T1)

Test Treatment Total (T2)

All Reasons for Discontinuations (ARD) (mandatory for studies that collect all reasons for discontinuation)

# 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 and Drug Discontinuation to Treatment Discontinuation as referenced in eCRF standard |  |
| 3.0 | Formatting update   * Footnote red box was corrected for alignment * study Treatment in footnote is changed to study treatment (small case for T) * Extra break link in the foot note was corrected   Consistency to other documents update   * Active Total changed to Test Treatment to align with the shell sub-title. |  |