STANDARD Table

T-DS04: Subject Disposition

VERSION 2.0

**ARD**

**ARD**

**R**

**O**

| TABLE 14.1\_\_x.x  **T1**  **T2**  Subject Disposition  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | | | | |
|  | | ----------------- Test Treatment ---------------- | | |  |
| Status | Control  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Total  (N=x)  n (%) | Total  (N=x)  n (%) |
|  |  |  |  |  |  |
| Randomized |  |  |  |  |  |
| Never received any study treatment | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Received randomized study treatment | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Received study treatment other than randomized | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Completed study phase | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Ongoing | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |  |
| Discontinued study | x (x.x) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| All reasons for discontinuation$ | 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 for discontinuation | 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 … \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study Phase: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reasons for Discontinuation: Obtain from data

# Optional Columns and Rows

All Total (T1)

Active Total (T2)

Randomized (R) (obtain from protocol, only applicable for randomized studies)

Ongoing (O)

All Reasons for Discontinuation (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 study drug to study treatment as referenced in eCRF standard |  |