STANDARD Table

T-AE07: TEAEs BY SOC, PT, and Maximum Relationship to Study Treatment

VERSION 2.0

| TABLE 14.3\_\_x.x  Subjects with Treatment-Emergent Adverse Events  by System Organ Class, Preferred Term and Maximum Relationship to Study Treatment  (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  | | --------------- Test Treatment ------------ | | |
| MedDRA xx.x System Organ Class  Preferred Term  Relationship | Control  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Total  (N=x)  n (%) |
|  |  |  |  |  |
| Any adverse event | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| No reasonable possibility | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reasonable possibility | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Unknown | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| System Organ Class | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| No reasonable possibility | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reasonable possibility | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Unknown | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |
| Preferred Term | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| No reasonable possibility | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Reasonable possibility | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Unknown | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |
| Note: Table depicts the most related adverse event for each preferred term as assessed by the investigator for each subject.  Subjects are counted once in each row within a column, regardless of the number of events they may have had. | | | | | |

**T2**

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

Analysis Population

Safety Analysis Set

Safety Population

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

Treatment Groups

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

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

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

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

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

MedDRA version: Obtain from data

System Organ Class and Preferred Term: Obtain from data

# Optional Columns and Rows

Test Treatment Total (T2)

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | Add “within a column” in the footnote. Updated Analysis Population options for consistency across all tables  Updated Test Drug to Test Treatment as referenced in eCRF standard  Changed “Active Total” to “Test Treatment Total” |  |