STANDARD Table

T-AE10: TEAEs by SOC, PT, and Maximum TOXICITY

VERSION 1.0

| TABLE 14.3\_\_x.x  Subjects with Treatment-Emergent Adverse Events  by System Organ Class, Preferred Term and Maximum Toxicity  (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  | | --------------- Test Treatment ----------- | | |
| MedDRA xx.x System Organ Class  Preferred Term  Toxicity | 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) |
| Grade 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 4  Grade 5  Unknown | x (x.x)  x (x.x)  x (x.x) | x (x.x)  x (x.x)  x (x.x) | x (x.x)  x (x.x)  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) |
| Grade 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 4  Grade 5  Unknown | x (x.x)  x (x.x)  x (x.x) | x (x.x)  x (x.x)  x (x.x) | x (x.x)  x (x.x)  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) |
| Grade 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Grade 4  Grade 5  Unknown | x (x.x)  x (x.x)  x (x.x) | x (x.x)  x (x.x)  x (x.x) | x (x.x)  x (x.x)  x (x.x) | x (x.x)  x (x.x)  x (x.x) |
|  |  |  |  |  |
| Note: Table depicts the most severe adverse event for each preferred term as assessed for each subject. Subjects are counted once in  each row within a column, regardless of the number of events they may have had. | | | | | |

# 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

Maximum Toxicity: Obtain from data

# Optional Columns and Rows

Test Treatment Total (T2)

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version based on TEAEs by Soc, PT, and Maximum Severity to have a separate table for Maximum toxicity  Below details are updated based on the V2.0 of the T-AE08 table  Add “within a column” in the footnote. Updated Analysis Population options for consistency across all tables based on other enterprise std  Updated Test Drug to Test Treatment as referenced in eCRF standard  Changed “Active Total” to “Test Treatment Total” |  |