STANDARD Table

T-AE09: AE by Subject Number

VERSION 2.0

| TABLE 14.3\_\_x.x  Subject Number Associated with Treatment-Emergent Adverse Events  by System Organ Class and Preferred Term  (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  | | -------------- Test Treatment ------------- | | |
| MedDRA xx.x System Organ Class  Preferred Term | Control  (N=x) | Arm 1  (N=x) | Arm 2  (N=x) | |
|  |  |  |  | |
| System Organ Class 1 |  |  |  | |
| Preferred Term 1 | x, x\*, x#, x\*# | x, x\*, x#, x\*# | x, x\*, x#, x\*# | |
| Preferred Term 2 | 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\*# | |
|  |  |  |  | |
| System Organ Class 2 |  |  |  | |
| Preferred Term 1 | x, x\*, x#, x\*# | x, x\*, x#, x\*# | x, x\*, x#, x\*# | |
| Preferred Term 2 | 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\*# | |
|  |  |  |  | |
| System Organ Class ... |  |  |  | |
| Preferred Term 1 | x, x\*, x#, x\*# | x, x\*, x#, x\*# | x, x\*, x#, x\*# | |
| Preferred Term 2 | 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\*# | |
|  |  |  |  | |
| \* Subject had a serious adverse event coded to this term.  # Subject had an adverse event that led to discontinuation coded to this term. | | | |

# 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

* Not applicable

# 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 as referenced in eCRF standard |  |