STANDARD Table

T-AE01: AE Overview (percent)

VERSION 4.0

| TABLE 14.3\_\_x.x  Overview of Treatment-Emergent Adverse Events and All Deaths  (Analysis Population) | | | | |
| --- | --- | --- | --- | --- |
|  | |  | | |
|  | | ---------------- Test Treatment -------------- | | |
|  | Control  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Total  (N=x)  n (%) |
|  |  |  |  |  |
| Subjects with any treatment-emergent |  |  |  |  |
|  |  |  |  |  |
| Adverse event (AE) | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE with reasonable possibility of being related to study treatment$ | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE with reasonable possibility of being related to study treatment 1$ | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE with possible, probable, causal relationship to study device$ | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE with possible, probable, causal relationship to study procedure $ | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Severity | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Serious AE | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE leading to withdrawal of study treatment | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE leading to withdrawal of study treatment 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE leading to removed study device | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE leading to aborted study procedure | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE results in death | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE category 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE category 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| AE category ... | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |
| All deaths | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Occurring <= xx days after last study treatment | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
| Occurring > xx days after last study treatment | x (x.x) | x (x.x) | x (x.x) | x (x.x) |
|  |  |  |  |  |
| Note: Subjects are counted once in each row within a column, regardless of the number of events they may have had.  $ As assessed by investigator. | | | | |
|  | | | | |

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

Defining TEAEs: number of post-treatment days for cut-off: xx days

# Optional Columns and Rows

Test Treatment Total (T2)

AE relationship to study treatment (REL)

Study treatment 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study device \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study procedure \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

AE leading to action taken of study treatment (ACT)

Study treatment 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study device \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Study procedure \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Severity (SEV)

Severe AE

AE with CTCAE Grade >=3

AE with CTCAE Grade 3 or 4

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

AE category (CAT)

AE category 1

AE category 2

AE category …\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | Change AESI to AE category and add COVID-19 infection |  |
| 3.0 | Add “within a column” in the footnote. Updated Analysis Population options for consistency across all tables  Added a solid line where applicable (ex. Study Treatment …)  Updated Test Drug to Test Treatment as referenced in eCRF standard  Severity AE is updated to have options to include Severe or CTCAE grade(s) as per feedback received from Oncology team on representing Severity when NCI CTCAE grade is used.  Changed “Active Total” to “Test Treatment Total” |  |
| 4.0 | 1. Remove COVID-19 infection 2. For optional rows, REL and AEW:  * Change ‘Study treatment 2’ to ‘Study device’ * Change ‘Study treatment 3’ to ‘Study procedure’ * Update the relationship and the action based on the updated standard eCRF for AE  1. For optional row, Day, change “last dose” to “last study treatment” to accommodate study device/procedure 2. CTCAE options list are updated to start with “AE with CTCAE Grade” instead of “CTCAE Grade” 3. Change the optional row reference of 'AEW’ to ‘ACT’. |  |