STANDARD Table

T-EX01: Extent of Exposure

VERSION 2.0

| TABLE 14.1\_\_x.x  **T2**  Extent of Exposure  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | -------------------- Test Treatment -------------------- | | | |
|  | Control  (N=x) | Arm 1  (N=x) | Arm 2  (N=x) | Total  (N=x) | |
|  |  |  |  |  | |
| Duration (day) |  |  |  |  | |
| n | x | x | x | x | |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | |
| Median | x | x | x | x | |
| Min, Max | x, x | x, x | x, x | x, x | |
|  |  |  |  |  | |
| Duration interval (day) - n (%) |  |  |  |  | |
| 1 - 15 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| 16 – 30 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| 31 – 45 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| 46 - 60 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| >60 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
|  |  |  |  |  | |
| Patient-years of exposure | x.x | x.x | x.x | x.x | |
|  |  |  |  |  | |
| Average dosed days per cycle (day) |  |  |  |  | |
| N | x | x | x | x | |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | |
| Median | x | x | x | x | |
| Min, Max | x, x | x, x | x, x | x, x | |
|  |  |  |  |  | |
| Number of doses |  |  |  |  | |
| n | x | x | x | x | |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | |
| Median | x | x | x | x | |
| Min, Max | x, x | x, x | x, x | x, x | |
|  |  |  |  |  | |
| Note: Duration of treatment = Last dose date – First dose date + 1. | | | | |

**NumD**

**Interval**

**Year**

**Avg**

| TABLE 14.1\_\_x.x  **T2**  Extent of Exposure  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | -------------------- Test Treatment -------------------- | | | |
|  | Control  (N=x) | Arm 1  (N=x) | Arm 2  (N=x) | Total  (N=x) | |
|  |  |  |  |  | |
| Number of cycles |  |  |  |  | |
| n | x | x | x | x | |
| Mean (SD) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | x.x (x.xx) | |
| Median | x | x | x | x | |
| Min, Max | x, x | x, x | x, x | x, x | |
|  |  |  |  |  | |
| Cycles – n (%) |  |  |  |  | |
| 1 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| 2 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| 3 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| 4 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| 5-10 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| 10-20 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
| >20 | x (x.x) | x (x.x) | x (x.x) | x (x.x) | |
|  |  |  |  |  | |
|  | | | | |

**NumC**

**Cycle**

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

Algorithm for duration of treatment to include in footnote: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Optional Columns and Rows

Duration Interval (Interval)

1-15

16-30

31-45

46-60

> 60

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

Patient-Years of Exposure (Year)

Average Dosed Days per cycle (day) (Avg)

Number of Doses (NumD)

Number of Cycles (NumC)

Cycles (Cycle)

1

2

3

4

5-10

11-20

> 20

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

Active Total (T2)

# 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 |  |