STANDARD Oncology Table

T-OCEF11: Treatment Duration and Time on Study

VERSION 1.0

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| --- | --- | --- | --- |
| TABLE 14.1\_\_x.x    Treatment Duration and Time on Study  (Analysis Population) | | | |
|  | | | |
|  |  | --------- Test Treatment -------- | |
| Comparator  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) |
|  |  |  |  |
| Overall treatment duration in duration unit [1] |  |  |  |
| n | x | x | x |
| Median | xx.x | xx.x | xx.x |
| Min, Max | xx, xx | xx, xx | xx, xx |
|  |  |  |  |
| Time on study in duration unit [2] |  |  |  |
| n | x | x | x |
| Median (95% CI) | xx.x (xx.x, xx.x) | xx.x (xx.x, xx.x) | xx.x (xx.x, xx.x) |
| Min, Max | xx, xx | xx, xx | xx, xx |

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| Note: Data cutoff date of DDMONYYYY.  CI=Confidence Interval.  [1] Treatment duration in duration unit is calculated as treatment duration calculation definition.  [2] Time on study is based on time on study calculation. |

OD

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

Analysis Population:

Full Analysis Set

Intent to Treat Population

Per-Protocol Population

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

Treatment Groups

Comparator\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

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

Duration Unit

Years

Months

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

# Optional Columns and Rows

Overall Treatment Duration (OD)

Footnotes (FN)

Note: Data cutoff date of \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Treatment duration calculation definition:

Continuous dosing:

(last dose date of study treatment – first dose date of study treatment + 1)/365.25

(last dose date of study treatment – first dose date of study treatment + 1)/30.4375

Intermittent dosing:

(first dose date of study treatment in last cycle + cycle length – first dose date of study treatment in first cycle)/30.4375

(first dose date of study treatment in last cycle + cycle length – first dose date of study treatment in first cycle)/365.25

Time on study calculation:

reverse Kaplan-Meier estimates of overall survival follow-up time

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# Special Programming Instructions (Optional)

The uses of the overall treatment duration is optional and would be provided for combination therapies. Individual therapy durations are captured on the treatment exposure table in 14.1.

# Version History

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| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |