STANDARD Oncology Table

T-OCEF02: Time to Event Summary

VERSION 2.0

| TABLE 14.2\_\_x.x  Analysis of Analysis Type  (Analysis Population) | | | |
| --- | --- | --- | --- |
|  |  | -------- Test Treatment --------- | |
|  | Comparator  (N=x) | Arm 1  (N=x) | Arm 2  (N=x) |
|  |  |  |  |
| Events – n (%) | x (x.x) | x (x.x) | x (x.x) |
| Death | x (x.x) | x (x.x) | x (x.x) |
| Disease Progression | x (x.x) | x (x.x) | x (x.x) |
| … |  |  |  |
| Censored – n (%) | x (x.x) | x (x.x) | x (x.x) |
| Study cutoff | x (x.x) | x (x.x) | x (x.x) |
| Study completion | x (x.x) | x (x.x) | x (x.x) |
| New anti-cancer therapy prior to PD/Death | x (x.x) | x (x.x) | x (x.x) |
| Two consecutive missed visits prior to PD | x (x.x) | x (x.x) | x (x.x) |
| No baseline assessment | x (x.x) | x (x.x) | x (x.x) |
| No post-baseline assessment | x (x.x) | x (x.x) | x (x.x) |
| Lost to follow-up | x (x.x) | x (x.x) | x (x.x) |
| Withdrew consent | x (x.x) | x (x.x) | x (x.x) |
|  | x (x.x) | x (x.x) | x (x.x) |
| Duration of PFS (months) |  |  |  |
| 25th [95% CI] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] |
| Median [95% CI] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] |
| 75th [95% CI] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] |
| … | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] |
| Min, Max | x.x, x.x+ | x.x, x.x | x.x, x.x+ |
|  |  |  |  |
| % KM Estimate at |  |  |  |
| 12 Month [95% CI] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] |
| 18 Month [95% CI] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] |
| 24 Month [95% CI] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] |
| … | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] | x.x [x.xx, x.xx] |
|  |  |  |  |
| Test Treatment vs Comparator |  |  |  |
|  |  |  |  |
| Stratified Tests$ |  |  |  |
| Hazard Ratio [95% CI]^ |  | x.xx [x.xx, x.xx] | x.xx [x.xx, x.xx] |
| Log-rank p-value |  | x.xxxx\* | x.xxxx |
| Wilcoxon p-value |  | x.xxxx\* | x.xxxx |
| … |  | x.xxxx\* | x.xxxx\* |
|  |  |  |  |
| Unstratified Tests |  |  |  |
| Hazard Ratio [95% CI]^ |  | x.xx [x.xx, x.xx] | x.xx [x.xx, x.xx] |
| Log-rank p-value |  | x.xxxx\* | x.xxxx |
| Wilcoxon p-value |  | x.xxxx\* | x.xxxx |
| … |  | x.xxxx\* | x.xxxx\* |
|  |  |  |  |

Note: Data cutoff date of DDMONYYYY.

IRC=Independent Review Committee, CI=Confidence interval, KM=Kaplan-Meier method. Analysis abbreviation

+ Indicates censored observation. ^ Hazard ratio is estimated using Cox proportional hazards model.

$ Stratified by stratification factors.

\* p-value <=0.05; \*\*p-value <=0.01; \*\*\*p-value <=0.001.

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

Analysis Type

Progression-Free Survival

Progression-Free Survival by IRC

Progression-Free Survival by BICR

Progression-Free Survival by INV

Overall Survival

Duration of Response

Duration of Response by IRC

Duration of Response by BICR

Duration of Response by INV

Event-Free Survival

Event-Free Survival by IRC

Event-Free Survival by BICR

Event-Free Survival by INV

Time To Progression

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

Analysis Population

Full Analysis Set

Intent to Treat Population

Per-Protocol Population

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

Treatment Groups

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

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

Test Treatment Arm 2\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Duration

PFS (months)

OS (months)

DoR (months)

TTP (months)

EFS (months)

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

Kaplan-Meier Estimate Timepoints

6 Month

12 Month

18 Month

24 Month

36 Month

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

# Optional Columns and Rows

Events (EV)

Death

Disease Progression

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

Censoring Reason (RE)

Study cutoff

Study completion

New anti-cancer therapy prior to PD/death

Two consecutive missed visits prior to PD

No baseline assessment

No post-baseline assessments

Lost to follow-up

Withdrew consent

COVID-19 infection/death

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

Percentiles (PERC)

25th [95% CI]

75th [95% CI]

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

Treatment arms for comparison

Test Treatment Arm 1 vs Comparator

Test Treatment Arm 2 vs Comparator

Test Treatment Arm 1 vs Test Treatment Arm 2

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ vs \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Hazard Ratio/P-values (HRPVS)

Stratified Tests

☐ Log-rank p-value

☐ Wilcoxon p-value

☐ Cox regression p-value

☐ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Hazard Ratio/P-values (HRPVU)

Unstratified Tests

☐ Log-rank p-value

☐ Wilcoxon p-value

☐ Cox regression p-value

☐ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Footnotes (FN)

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

IRC = Independent Review Committee

BICR = Blinded Independent Central Review

INV = Investigator

Analysis abbreviation (i.e., PFS=Progression-Free Survival): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Stratified by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Hazard ratio is estimated using\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\* p-value <=0.05; \*\*p-value <=0.01; \*\*\*p-value <=0.001.

\* p-value <=\_\_\_\_\_\_

# Special Programming Instructions

If additional comparisons between test treatment arms are required, mark under ‘Treatment arms for comparison’ the box for ‘Test Treatment Arm 1 vs Test Treatment Arm 2’. This will identify the need to generate a new set of HR/p-values boxes for this comparison.

For duration of KM estimates other than 25%, median, and 75%, simulation calculations will need to be provided in SPP for programming, as SAS does not provide these estimates.

For values either not reach or not estimable, use ‘NE’ with table.

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | Added ‘Test Treatment’ to arms, added censoring reasons option, fix stratified footnote option, added treatment arm comparison option, added ’Note:’ to cutoff date, added Blinded Independent Central Review (BICR) option, allow user specified p-value, added special programming instruction which include guidance on treatment comparisons, KM estimates other than 25%, median, or 75%, and recommend using ‘NE’ in table when a value is either not reached or not estimable. |  |