STANDARD Oncology Table For RECIST

T-OCEF01: Response Rate

VERSION 3.0

| TABLE 14.2\_\_1.2  Analysis of Response Rates by Analysis type  (Analysis Population) | | | | | |
| --- | --- | --- | --- | --- | --- |
|  | | ------- Test Treatment ------- | | ---------- P-value@ ---------- | |
| Response  Type of Response | Comparator  (N=x)  n (%) | Arm 1  (N=x)  n (%) | Arm 2  (N=x)  n (%) | Arm 1  vs  Comparator | Arm 2  vs  Comparator |
|  |  |  |  |  |  |
| Objective Response Rate (CR+PR) | x (x.x) | x (x.x) | x (x.x) | x.xxxx\* | x.xxxx |
| [95% CI]# | [x.xx, x.xx] | [x.xx, x.xx] | [x.xx, x.xx] |  |  |
|  |  |  |  |  |  |
| Difference in Rates |  | x.x | x.x |  |  |
| [95% CI]# |  | [x.xx, x.xx] | [x.xx, x.xx] |  |  |
|  |  |  |  |  |  |
| Rate Ratio |  | x.x | x.x |  |  |
| [95% CI]# |  | [x.xx, x.xx] | [x.xx, x.xx] |  |  |
|  |  |  |  |  |  |
| Complete Response (CR) | x (x.x) | x (x.x) | x (x.x) |  |  |
| [95% CI]# | [x.xx, x.xx] | [x.xx, x.xx] | [x.xx, x.xx] |  |  |
|  |  |  |  |  |  |
| Partial Response (PR) | x (x.x) | x (x.x) | x (x.x) |  |  |
| [95% CI]# | [x.xx, x.xx] | [x.xx, x.xx] | [x.xx, x.xx] |  |  |
|  |  |  |  |  |  |
| Clinical Benefit Rate (CR+PR+SD) | x (x.x) | x (x.x) | x (x.x) |  |  |
| [95% CI]# | [x.xx, x.xx] | [x.xx, x.xx] | [x.xx, x.xx] |  |  |
|  |  |  |  |  |  |
| Best Overall Response |  |  |  |  |  |
| Complete Response (CR) | x (x.x) | x (x.x) | x (x.x) |  |  |
| Partial Response (PR) | x (x.x) | x (x.x) | x (x.x) |  |  |
| Stable Disease (SD) | x (x.x) | x (x.x) | x (x.x) |  |  |
| Progressive Disease (PD) | x (x.x) | x (x.x) | x (x.x) |  |  |
| Confirmed Progressive Disease (CPD) | x (x.x) | x (x.x) | x (x.x) |  |  |
| Unconfirmed Progressive Disease (UPD) | x (x.x) | x (x.x) | x (x.x) |  |  |
| … | x (x.x) | x (x.x) | x (x.x) |  |  |
|  |  |  |  | |  |

Note: Data cutoff date of DDMONYYYY.

IRC = Independent Review Committee, CI = Confidence Interval.

@ P-value is from p-value method test stratified by stratification factors.

# 95% confidence interval is from the exact binomial distribution.

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

# 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 2 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Analysis type

Investigator

IRC

# Optional Columns and Rows

P-Value Required (PV)

Arm 1 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ vs Comparator \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

Objective Response Rate (CR+PR) (ORR)

Difference in Rates (DIF)

Ratio (RR)

Odd Ratio

Rate Ratio

Complete Response (CR)

Partial Response (PR)

Clinical Benefit Rate (CR+PR+SD) (CBR)

Best Overall Response (BOR)

Complete Response (CR)

Partial Response (PR)

Stable Disease (SD)

Progressive Disease (PD)

Confirmed Progressive Disease (CPD)

Unconfirmed Progressive Disease (UPD)

Not-Evaluable (NE)

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

Footnotes (FN)

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

IRC = Independent Review Committee

P-value method\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Stratification factors \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

\* p-value <=\_\_\_\_\_\_

# Version History

|  |  |  |
| --- | --- | --- |
| **Version** | **Description** | **Effective Date** |
| 1.0 | Initial version describing how to add functionality to standard TLF shells |  |
| 2.0 | Updated to include difference between arms and risk ratio. Updated format to match current standards |  |
| 3.0 | Changes Include:   * Modified Active header to be Test Treatment header. * Added Test Treatment to each arm in study specific text. * Updated PD to be Progressive Disease instead of Disease Progression. * Added ‘Rate’ to the Objective Response option. * Capitalized the Best Overall Response (BOR) options. * Added ‘Note:’ to cutoff date. * Fixed spacing in footnotes. * Allow user specified p-value option. |  |