RCT project

Client name

Alexandre Bohyn

Table of contents

# 1. Descriptive statistics

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 1: Descriptive statistics of the TRIAL dataset.   | **Characteristic** | **Overall**  N = 2001 | **Drug A**  N = 981 | **Drug B**  N = 1021 | **p-value**2 | | --- | --- | --- | --- | --- | | Age at enrollment (years) |  |  |  | 0.7 | | Mean (SD) | 47.2 (14.3) | 47.0 (14.7) | 47.4 (14.0) |  | | Median (Q1, Q3) | 47.0 (38.0, 57.0) | 46.0 (37.0, 60.0) | 48.0 (39.0, 56.0) |  | | Unknown | 11 | 7 | 4 |  | | Biomarker level |  |  |  | 0.085 | | Mean (SD) | 0.9 (0.9) | 1.0 (0.9) | 0.8 (0.8) |  | | Median (Q1, Q3) | 0.6 (0.2, 1.4) | 0.8 (0.2, 1.6) | 0.5 (0.2, 1.2) |  | | Unknown | 10 | 6 | 4 |  | | Tumor stage |  |  |  | 0.9 | | T1 | 53 (27%) | 28 (29%) | 25 (25%) |  | | T2 | 54 (27%) | 25 (26%) | 29 (28%) |  | | T3 | 43 (22%) | 22 (22%) | 21 (21%) |  | | T4 | 50 (25%) | 23 (23%) | 27 (26%) |  | | Tumor grade |  |  |  | 0.9 | | I | 68 (34%) | 35 (36%) | 33 (32%) |  | | II | 68 (34%) | 32 (33%) | 36 (35%) |  | | III | 64 (32%) | 31 (32%) | 33 (32%) |  | | Response to treatment | 61 (32%) | 28 (29%) | 33 (34%) | 0.5 | | Unknown | 7 | 3 | 4 |  | | Death | 112 (56%) | 52 (53%) | 60 (59%) | 0.4 | | Time to event (days) |  |  |  | 0.14 | | Mean (SD) | 19.6 (5.3) | 20.2 (5.0) | 19.0 (5.5) |  | | Median (Q1, Q3) | 22.4 (15.9, 24.0) | 23.5 (17.4, 24.0) | 21.2 (14.5, 24.0) |  | | 1n (%) | | | | | | 2Wilcoxon rank sum test; Pearson's Chi-squared test | | | | | |

# 2. Survival analysis

|  |
| --- |
| Figure 1: Kaplan-Meier curve per treatment group. |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Table 2: Cox proportional hazards model results.   | **Characteristic** | **HR** | **95% CI** | **p-value** | | --- | --- | --- | --- | | Treatment group |  |  | 0.12 | | Drug A | — | — |  | | Drug B | 1.36 | 0.92, 2.01 |  | | Tumor stage |  |  | <0.001 | | T1 | — | — |  | | T2 | 1.34 | 0.75, 2.37 |  | | T3 | 1.30 | 0.70, 2.42 |  | | T4 | 2.96 | 1.69, 5.21 |  | | Tumor grade |  |  | 0.10 | | I | — | — |  | | II | 1.25 | 0.75, 2.06 |  | | III | 1.67 | 1.04, 2.68 |  | | Age at enrollment (years) |  |  | 0.2 | | rcs(age, 4)age | 1.04 | 0.98, 1.10 |  | | rcs(age, 4)age' | 0.90 | 0.78, 1.04 |  | | rcs(age, 4)age'' | 1.62 | 0.85, 3.09 |  | | Abbreviations: CI = Confidence Interval, HR = Hazard Ratio | | | | |