Example Report

Kirsten Bell Burdett

15 Feb 2020

Contents

Data:

```
readfile <- file.path(dir, "FakeExampleAEs.csv")
fakeAEdat <- read_csv(readfile)
tools::md5sum(readfile)
```

```
## /Volumes/fsmhome/Dynamic_reporting_presentation/Data//FakeExampleAEs.csv
##                                       "cb2247c25d3ed473e0e531a8f97a04a7"
```

/FakeExampleAEs.csv
cb2247c25d3ed473e0e531a8f97a04a7

Veteran Data:
We will be using the veteran data from the survival package. The original data has 137 subjects, but we will be subsetting to only those subjects that have test treatment and cell type of squamous, smallcell, or adeno which will result in 56 subjects.

Background

Protocol Title Here. This is a great place to have background information about the study as well as include your statistical analysis plan (SAP).

Objectives

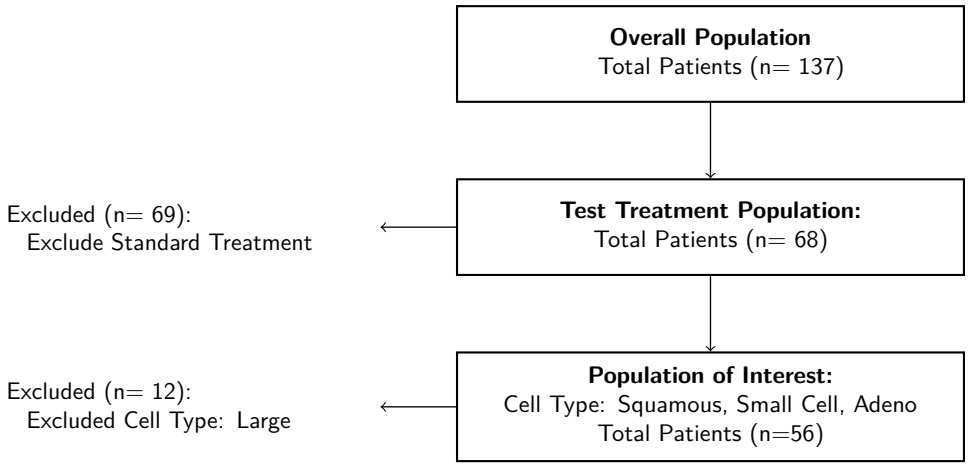
Primary Objective:

- Define Here

Secondary Objective:

- Define Here

CONSORT Flow Diagram



Baseline Patient Demographic and Clinical Characteristics

```
kable(testtab, longtable = TRUE, booktabs = TRUE, caption = "Demographics for Population of Interest") %>%
  kable_styling(latex_options = c("striped","HOLD_position", "repeat_header")) %>%
  footnote(general = "Footnote Here.", general_title = "")
```

Table 1: Demographics for Population of Interest

	level	Overall
n		56
Cell Type (%)	squamous	20 (35.7)
	smallcell	18 (32.1)
	adeno	18 (32.1)
Karnofsky Performance Score (mean (SD))		57.75 (22.06)
Age in Years (mean (SD))		59.43 (10.05)
Prior Therapy (%)	No	42 (75.0)
	Yes	14 (25.0)

Footnote Here.

Primary Objective

Primary Objective: Define HERE

Adverse Events

```
kable(makepretty(fakeAEdat, "anyRAE"), longtable = TRUE, booktabs = TRUE, caption = "All Related Adverse E
  kable_styling(latex_options = c("striped", "repeat_header")) %>%
  row_spec(1, bold = TRUE ) %>%
  column_spec(1, width = "15em") %>%
  footnote(general = "Frequencies use the total number of subjects in the overall population as the denomi
```

Table 2: All Related Adverse Events by Grade: for each subject that had at least one event in the overall population.

Event	Grade 1	Grade 2	Grade 3	Grade 4
	9	**7**	**1**	**1**
Anemia	0	1 (0.73%)	0	0
Chills	1 (0.73%)	0	0	0
Cough	1 (0.73%)	0	0	0
Diarrhea	1 (0.73%)	0	0	0
Fatigue	1 (0.73%)	2 (1.46%)	0	0
Headache	2 (1.46%)	0	0	0
Memory impairment	0	1 (0.73%)	0	0
Nausea	1 (0.73%)	0	0	1 (0.73%)
Nervous system disorders	0	1 (0.73%)	0	0
Non-cardiac chest pain	1 (0.73%)	0	0	0
Syncope	0	0	1 (0.73%)	0
Upper respiratory infection	0	1 (0.73%)	0	0
Vomiting	1 (0.73%)	1 (0.73%)	0	0

Frequencies use the total number of subjects in the overall population as the denominator. The first row indicates event totals.

Survival Outcomes

For population of interest (n=56) the 6 and 12 unit OS probability for the overall population was 0.964 and 0.876 respectively. 6 and 12 unit OS probability for the population of interest was 0.946 and 0.875 respectively.

Population	Median (CI)
OS - Overall Population	80 (52 , 105)
OS - Population of Interest	51.5 (33 , 95)

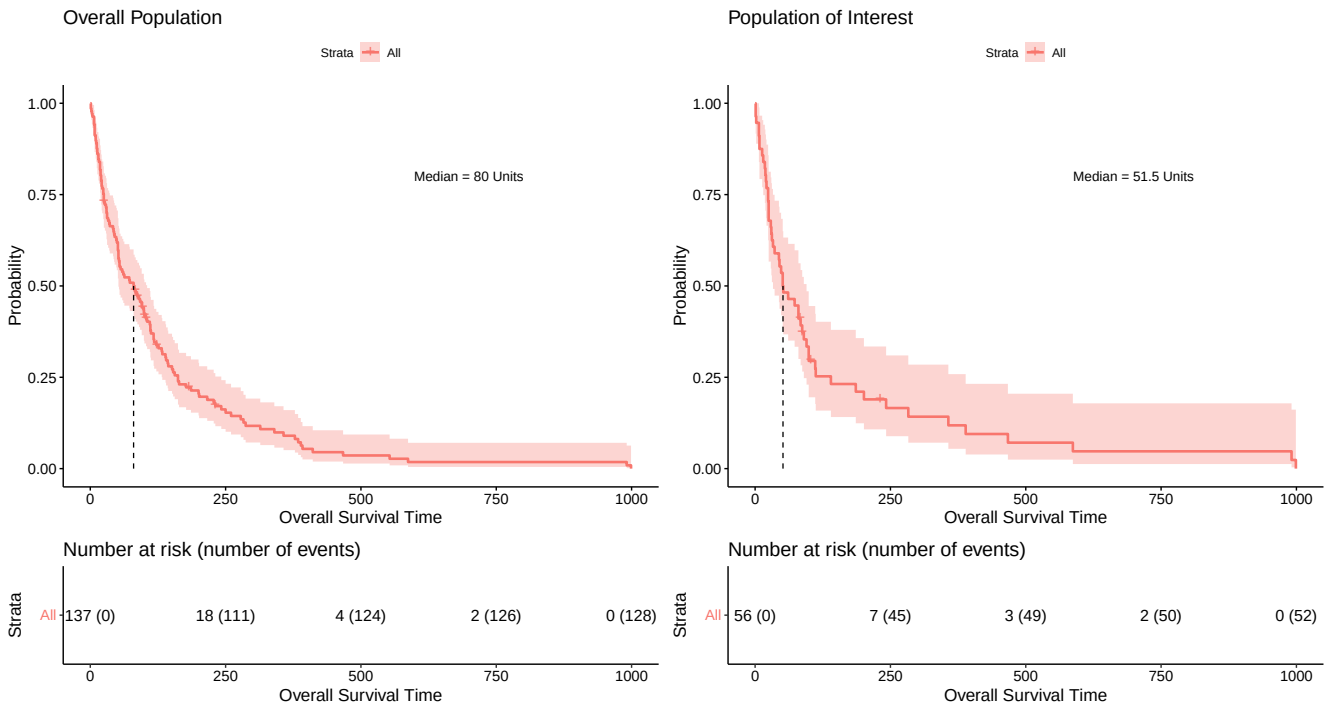


Figure 1: Kaplan-Meier plots for overall survival.

Supplementary

Survival Analysis Equation Example:

The Kaplan-Meier method is a non-parametric procedure which is sensitive to the choice of time interval and assumes that events of individuals are independent. We will denote the jth event time as $t_{(j)}$. The number at risk before $t_{(j)}$ is denoted as n_j where $n_{j+1} = n_j - d_j - c_j$ where c_j is the number of censored observations. The number of events at $t_{(j)}$ is denoted by d_j. The estimated survival function given below can be interpreted as the probability of survival through the interval $t_{(k)} \leq t < t_{(k+1)}$ where k = 1,2...r where r is the event time.

$$\hat{S}(t) = \prod_{j=1}^{k} \frac{n_j - d_j}{n_j}, \qquad t_{(k)} \leq t < t_{(k+1)}$$

The hazard is then estimated by taking the ratio of d_j compared to $n_j \tau_{(j)}$ where $\tau_{(j)}$ is the length of the jth time interval $(t_{(j+1)} - t_{(j)})$.

$$\hat{h}(t) = \frac{d_j}{n_j \tau_j}, \qquad t_{(j)} \leq t < t_{(j+1)}$$

Session Information

- R version 3.5.3 (2019-03-11), `x86_64-apple-darwin15.6.0`
- Running under: `macOS High Sierra 10.13.6`
- Matrix products: default
- BLAS: `/Library/Frameworks/R.framework/Versions/3.5/Resources/lib/libRblas.0.dylib`
- LAPACK: `/Library/Frameworks/R.framework/Versions/3.5/Resources/lib/libRlapack.dylib`
- Base packages: base, datasets, graphics, grDevices, methods, stats, utils
- Other packages: dplyr 0.8.0.1, forcats 0.4.0, ggplot2 3.1.1, ggpubr 0.2, kableExtra 1.1.0, knitr 1.22, magrittr 1.5, purrr 0.3.2, readr 1.3.1, stringr 1.4.0, survival 2.44-1.1, survminer 0.4.3, tableone 0.10.0, tibble 2.1.1, tidyr 0.8.3, tidyverse 1.2.1
- Loaded via a namespace (and not attached): assertthat 0.2.1, backports 1.1.4, broom 0.5.2, cellranger 1.1.0, class 7.3-15, cli 1.1.0, cmprsk 2.2-7, colorspace 1.4-1, compiler 3.5.3, crayon 1.3.4, data.table 1.12.2, DBI 1.0.0, digest 0.6.18, e1071 1.7-3, evaluate 0.13, generics 0.0.2, glue 1.3.1, grid 3.5.3, gridExtra 2.3, gtable 0.3.0, haven 2.1.0, hms 0.4.2, htmltools 0.3.6, httr 1.4.0, jsonlite 1.6, km.ci 0.5-2, KMsurv 0.1-5, labeling 0.3, labelled 2.2.2, lattice 0.20-38, lazyeval 0.2.2, lubridate 1.7.4, Matrix 1.2-15, mitools 2.4, modelr 0.1.4, munsell 0.5.0, nlme 3.1-137, pillar 1.3.1, pkgconfig 2.0.2, plyr 1.8.4, R6 2.4.0, Rcpp 1.0.1, readxl 1.3.1, rlang 0.3.4, rmarkdown 1.13, rstudioapi 0.10, rvest 0.3.3, scales 1.0.0, splines 3.5.3, stringi 1.4.3, survey 3.37, survMisc 0.5.5, tidyselect 0.2.5, tools 3.5.3, viridisLite 0.3.0, webshot 0.5.1, withr 2.1.2, xfun 0.6, xml2 1.2.0, xtable 1.8-3, yaml 2.2.0, zoo 1.8-5

```
## [1] "Start Time Sat Feb 15 21:29:15 2020"
```

```
## [1] "End Time   Sat Feb 15 21:29:20 2020"
```