R code snippet for:

Methods for implementing and reporting the Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events to measure patient-reported adverse events in cancer clinical trials

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```
#ProAE v1.0.3
library(ProAE)
#?ProAE

library(ggplot2)
#?ggplot2

#generate monotonic missing data in ProAE simulated data using exp distribution after cycle 2
#add intermittent missing data using unif distribution after cycle 1
set.seed(500)

N <- 140

y_rexp <- rexp(N, rate = 0.1)
mean(y_rexp)
last_cycle <- rep(2,140) + floor(y_rexp)
last_cycle_long <- rep(last_cycle,each=10)

missing_ind <- c(0,runif(9))

for (i in 1:69) {
  temp1 <- missing_ind
  temp2 <- c(0,runif(9))
  missing_ind <- c(temp1, temp2)
}
mean(missing_ind)
```

```
cumu <- ProAE::tox_cumulative
cumu2 <- cbind(cumu,last_cycle_long,missing_ind)
cumu3 <- subset(cumu2, Cycle<=last_cycle_long)
cumu4 <- subset(cumu3,missing_ind<0.92)

str(cumu4)

figure_1 <- toxFigures(dsn=cumu4,
           id_var="id",
           cycle_var="Cycle",
           baseline_val=1,
           arm_var="arm",
           plot_limit = 7,
           colors = 2,
           bar_label = 1,
           cycle_label = TRUE,
           cycle_vals = c(1,2,3,4,5,6,7),
           cycle_labs = c('Baseline','Cycle 1','Cycle 2','Cycle 3','Cycle 4','Cycle 5','Cycle 6'),
           summary_only = FALSE,
           summary_highlight = TRUE,
           cycles_only = FALSE,
           x_lab_angle = 45,
           x_lab_vjust = 1,
           x_lab_hjust = 1,
           x_label = "Randomized Treatment Assignment",
           y_label = "Percent of Total Frequency",
           footnote_break = FALSE,
           suppress_legend = FALSE,
           add_item_title = FALSE
)

#Figure 1
figure_1[[1]][2]

require(knitr)
require(kableExtra)

table_1 <- toxTables(dsn = cumu4,
                     id_var="id",
                     cycle_var="Cycle",
                     baseline_val = 1,
                     arm="arm",
                     riskdiff=TRUE)

knitr::kable(table_1$individual)
knitr::kable(table_1$composite)
```

```
knitr::kable(table_1$individual,
             col.names = c('Item/Attribute', 'Drug', 'Placebo', 'Drug', 'Placebo',
             "Risk Difference (Wald 95% CI)", "Drug", "Placebo", "Risk Difference (Wald 95% CI)"),
             caption = "Table 1A. Proportion of patients with PRO-CTCAE score >=1 and >=3, by treatment
             arm") %>%
kableExtra::add_header_above(c(" ", "n" = 2,  "Score >=1" = 2, " ", "Score >=3" = 2, " "))

knitr::kable(table_1$composite,
             col.names = c('Item/Attribute', 'Drug', 'Placebo', 'Drug', 'Placebo',
             "Risk Difference (Wald 95% CI)", "Drug", "Placebo", "Risk Difference (Wald 95% CI)"),
             caption = "Table 1B. Proportion of patients with PRO-CTCAE composite score >=1 and >=3, by
             treatment arm") %>%
kableExtra::add_header_above(c(" ", "n" = 2,  "Score >=1" = 2, " ", "Score >=3" = 2, " "))
```

Outputs:

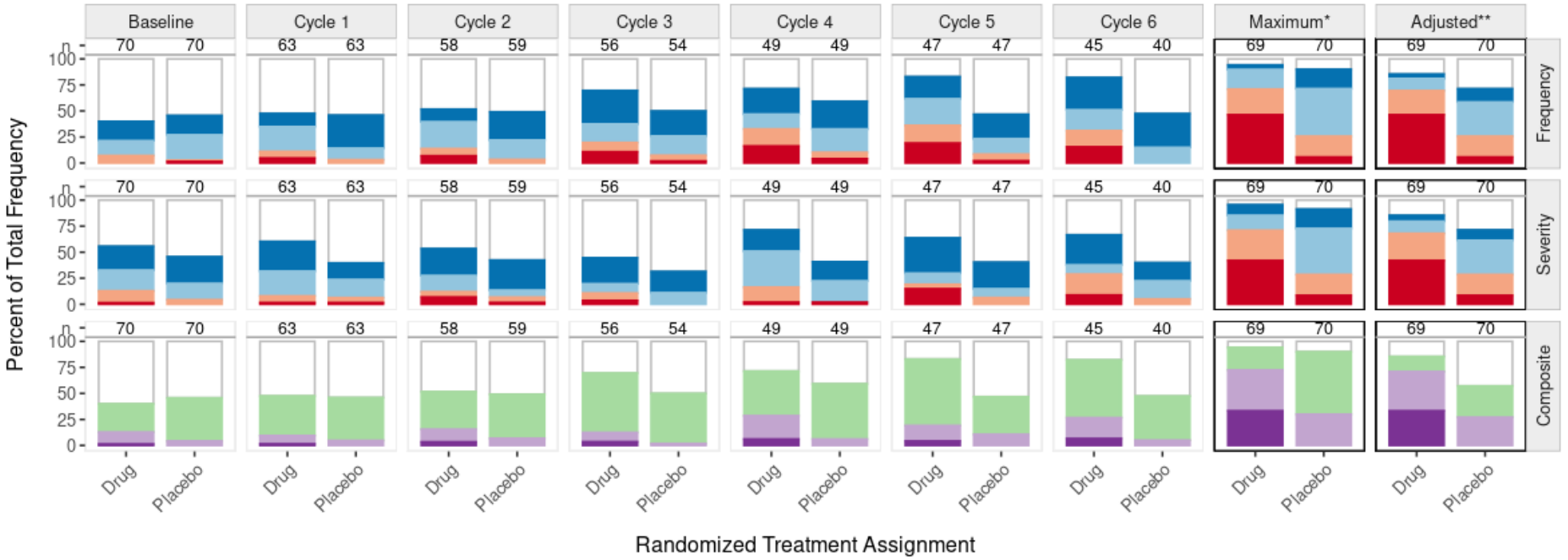

Table 1A. Proportion of patients with PRO-CTCAE score >=1 and >=3, by treatment arm

	n		Score >=1			Score >=3		
Item/Attribute	**Drug**	**Placebo**	**Drug**	**Placebo**	**Risk Difference (Wald 95% CI)**	**Drug**	**Placebo**	**Risk Difference (Wald 95% CI)**
Nausea Frequency	69	70	59 (86%)	50 (71%)	14% (1%, 28%)	48 (70%)	18 (26%)	44% (29%, 59%)
Nausea Severity	69	70	59 (86%)	50 (71%)	14% (1%, 28%)	47 (68%)	20 (29%)	40% (24%, 55%)

Table 1B. Proportion of patients with PRO-CTCAE composite score >=1 and >=3, by treatment arm

	n		Score >=1			Score >=3		
Item/Attribute	**Drug**	**Placebo**	**Drug**	**Placebo**	**Risk Difference (Wald 95% CI)**	**Drug**	**Placebo**	**Risk Difference (Wald 95% CI)**
Nausea	69	70	59 (86%)	40 (57%)	28% (14%, 43%)	23 (33%)	0 (0%)	33% (22%, 44%)