PP17: Creation of Adverse Event (AE) Table using R Programming

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BACKGROUND

GOAL

To Create Adverse Event (AE) table of clinical trial using R.

Steps to create AE Table in R

Step 1: - Setup
Step 2 - Selection of records/variables
Step 3: Select Highest Toxicity Grade AEs
Step 4: Get Freq and Calculate % - ANY AE / SOC/ SOC-PT
Step 5: Data Arrangement
Step 6: Transpose Data
Step 7: Reporting Prep
Step 8: Reporting

PROGRAMMING STEPS

 # Step: 1 - Setup

```
library("tidyverse")
library("kableExtra")
library("rtf")

adae <- read.csv(file = "F:/R/adae.csv",
    fileEncoding="UTF-8-BOM",
    blank.lines.skip = TRUE,header = TRUE)
```

Import Data.(Like PROC IMPORT in SAS)

 # Step: 2 - Selection of records/variables

```
adae2 <- subset(adae, SAFFL=="Y",
     select = c(USUBJID, AEBODSYS, AEDECOD,
AETOXGR, TRTA, TRTAN))

#Sorting
adae3 <- adae2[order(adae2$AEBODSYS,
adae2$AEDECOD, -adae2$AETOXGR),]
```

Select safety pop& keep variables # Sorting

 # Step 3: Select Highest Toxicity Grade AEs

```
any_ae <- adae3 %>%
  group_by(USUBJID, TRTA) %>%
  arrange(USUBJID, TRTA, -AETOXGR)%>%
  slice_head(n=1)
```

Same way for "Any SOC" and "Any SOC/PT"
Change only in

```
group_by(USUBJID, TRTA, AEBODSYS) %>%
arrange(USUBJID, TRTA,AEBODSYS, -AETOXGR)%>%
```

 # Step 4: Get Freq and Calculate % - ANY AE

```
any_ae1 <- any_ae %>%
  group_by(TRTA,TRTAN)%>%
  summarise(n=n(),.groups = "keep") %>%
  mutate( pct = if_else(TRTAN == '1',
n*100/bign[1], n*100/bign[2] ),
    ORD1=0,
    ORD2=0,
    txt="Total Subjects with an Event",
    AEBODSYS="Total Subjects with an Event",
    AEDECOD = " "    )
```

Get stat for ANY SOC & ANY PT

 # Step: 5 - Data Arrangement

```
all_ae <- rbind(any_ae1, any_bodsys1, any_decod1)
all_ae1 <- all_ae[order(all_ae$TRTA,
all_ae$ORD1,all_ae$AEBODSYS, -all_ae$ORD2, -
all_ae$ORD3),]    #Ordering
#Create Freq (PCT) variable
all_ae2 <- all_ae1 %>%
 mutate(var1 = paste (n,"(",format(round(pct,
digits = 2),nsmall = 2),")"),
 TRTA = ifelse(TRTA=="Active Drug A",
"DrugA","Placebo"))
```

Stacking all DS | Ordering | Creation of PCT variable

 # Step: 6 - Transpose Data

```
t_ae <- all_ae2 %>%
  ungroup()%>%
select(-TRTAN,-n,-pct,-AEDECOD,-ORD3)%>%
spread(TRTA, var1) %>%
mutate(DrugA= ifelse(is.na(DrugA),0,
DrugA), Placebo =
ifelse(is.na(Placebo),0, Placebo) )%>%
arrange(ORD1, AEBODSYS, ORD2)
t_ae1 <- subset(t_ae, select=c(-ORD1, -
ORD2, -AEBODSYS))
```

Transpose keeping AE in BY
Drop vars

 # Step: 7 - Reporting Prep

```
t1<- paste(rep(' ',30,),collapse = "
")
t2<- paste(rep(' ',33,),collapse = "
")
title1 <- "Adverse Event Summary <br/>"
title2<- "Safety Population<br/>"
titleX <- paste(t1,title1,t2,title2,
collapse = '')
```

Preparing titles

 # Step: 8 - Reporting

```
#Using KTable or kble
kbl(x = t_ae1,
   col.names = c(" ", "Drug A", "Placebo" ),
   caption = titleX,
   escape = FALSE , longtable = T) %>%
 kable_paper("striped", full_width = F) %>%
 add_header_above(c(" " = 3))%>%
footnote(general =c("AE is calculated at highest toxicity
grade.", "Subject is counted once in each PT.")) %>%
  column_spec(1,width="12cm" ) %>%
  column_spec(2,width ="3cm" ) %>%
  column_spec(3,width = "3cm",popover = "Test" ) %>%
  save_kable(file = "table1.html", self_contained = T)
```

Preparing titles
Using Ktable > Generating output.

COMPARISON OF R WITH SAS

In R

1. read.csv > read ext file
2. subset > subset obs and variables in data
3. order > Sorting data
4. %>% (pipe) – for multiple action & one's ourput pass next
5. group_by > grouping of records
6. arrange > order obs
7. slice_head>take 1st ob.
8. summarise > get stats
9. mutate > creation of var and manipulations
10. rbind > stacking datasets
11. spread > transpose
12. kbl > reporting

In SAS

1. PROC IMPORT
2. Keep/Drop AND WHERE conditions
3. PROC SORT
4. Similar (not exactly) – multiple statements in one Data Step
5. By statement > for grouping
6. PROC SORT
7. Like FIRST. and LAST.
8. Like PROC FREQ
9. Like DATA Step
10. SET statement> stacking
11. PROC TRANSPOSE
12. Proc REPORT

AE Mock Shell

Adverse Event Summary
Safety Population

System Organ Class (%) Preferred Term (%)	Placebo N=xxx	Treatment A N=xxx
TOTAL SUBJECTS WITH AN EVENT	XXX (XX.X)	XXX (XX.X)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	XXX (XX.X)	XXX (XX.X)
ANAEMIA	XX (X.X)	XX (X.X)
LEUKOPENIA	XX (X.X)	XX (X.X)
EOSINOPHILIA	XX (X.X)	XX (X.X)
LYMPHADENOPATHY	X (X.X)	XX (X.X)
LEUKOCYTOSIS	X (X.X)	XX (X.X)
THROMBOCYTOPENIA	X (X.X)	XX (X.X)
IRON DEFICIENCY ANAEMIA	X (X.X)	X (X.X)
BONE MARROW TOXICITY	X (X.X)	X (X.X)
ANAEMIA FOLATE DEFICIENCY	X (X.X)	X (X.X)
ANAEMIA OF CHRONIC DISEASE	X (X.X)	X (X.X)
CARDIAC DISORDERS	XXX (XX.X)	XX (X.X)
PALPITATIONS	XX (X.X)	X (X.X)
TACHYCARDIA	XX (X.X)	X (X.X)
CARDIAC FAILURE CONGESTIVE	XX (X.X)	X (X.X)
BRADYCARDIA	X (X.X)	X (X.X)
SINUS BRADYCARDIA	X (X.X)	X (X.X)
ARRHYTHMIA	X (X.X)	X (X.X)
ATRIAL FIBRILLATION	X (X.X)	X (X.X)
UNASSIGNED	X (X.X)	X (X.X)
UNASSIGNED	X (X.X)	X (X.X)

MedDRA Version: XX.X

Final output

AE Output

Adverse Event Summary
Safety Population

	Drug A	Placebo
Total Subjects with an Event	28 (100.00)	27 (100.00)
Blood and lymphatic system disorders	3 (10.71)	5 (18.52)
Anaemia	3 (10.71)	5 (18.52)
Cardiac disorders	0	3 (11.11)
Atrial fibrillation	0	1 (3.70)
Palpitations	0	1 (3.70)
Pericardial effusion	0	1 (3.70)
Ear and labyrinth disorders	1 (3.57)	0
Vertigo	1 (3.57)	0
Endocrine disorders	3 (10.71)	1 (3.70)
Hyperthyroidism	2 (7.14)	1 (3.70)
Hypothyroidism	2 (7.14)	0
...		
Skin and subcutaneous tissue disorders	5 (17.86)	6 (22.22)
Hyperhidrosis	1 (3.57)	0
Night sweats	0	1 (3.70)
Pruritus	3 (10.71)	5 (18.52)
Rash	2 (7.14)	0

Note:
AE is calculated at highest toxicity grade.
Subject is counted once in each PT.

For any questions, Please contact -
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