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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 underline variables **
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: 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)
ANEMIA	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 ANEMIA	X (X.X)	X (X.X)
BONE MARROW TOXICITY	X (X.X)	X (X.X)
ANEMIA FOLATE DEFICIENCY	X (X.X)	X (X.X)
ANEMIA 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)

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

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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