The Summary Treatment Emergent Adverse Event by Body System and Preferred Term Table

Using R (SASSY, Pharmaverse and Tidyverse)

Authored by David Franklin, TheProgrammersCabin.com, 2026-11-13 (Page 1 of 2)

The ADAE

	USUBJID Unique Su...	ARM Description of Plann...	ARMCD Planned A...	SAFFL Safety P...	TRTEMFL Treatment E...	AEDECOD Dictionary-Derived Term	AEBODSYS Body System or Organ Class
1	01-701-1015	Placebo	Pbo	Y	Y	APPLICATION SITE ERYTHEMA	GENERAL DISORDERS AND ADMINISTRATION SITE
2	01-701-1015	Placebo	Pbo	Y	Y	APPLICATION SITE PRURITUS	GENERAL DISORDERS AND ADMINISTRATION SITE
3	01-701-1015	Placebo	Pbo	Y	Y	DIARRHOEA	GASTROINTESTINAL DISORDERS
4	01-701-1023	Placebo	Pbo	Y	Y	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS
5	01-701-1023	Placebo	Pbo	Y	Y	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS
6	01-701-1023	Placebo	Pbo	Y	Y	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS
7	01-701-1023	Placebo	Pbo	Y	Y	ATRIOVENTRICULAR BLOCK SECOND DEGREE	CARDIAC DISORDERS
8	01-701-1028	Xanomeline High Dose	Xan_Hi	Y	Y	APPLICATION SITE ERYTHEMA	GENERAL DISORDERS AND ADMINISTRATION SITE

The Output

Sponsor: Yum, Yum and Yum Inc. Study: Sweet Sauce III

Table 14.3-2
Summary of Treatment-Emergent Adverse Events by Body System, Preferred Term and Treatment
Safety Population

	Placebo (N=86)		Xanomeline High Dose (N=84)		Xanomeline Low Dose (N=84)		All Xanomeline (N=168)	
System Organ Class Preferred Term	n (%)	Events	n (%)	Events	n (%)	Events	n (%)	Events
Any Adverse Event	65 (75.6)	281	75 (89.3)	429	77 (91.7)	412	152 (90.5)	841
CARDIAC DISORDERS	12 (14.0)	26	15 (17.9)	30	13 (15.5)	30	28 (16.7)	60
ATRIAL FIBRILLATION	1 (1.2)	1	3 (3.6)	5	1 (1.2)	1	4 (2.4)	6
ATRIAL FLUTTER	0	0	1 (1.2)	2	1 (1.2)	1	2 (1.2)	3
ATRIAL HYPERTROPHY	1 (1.2)	2	0	0	0	0	0	0
ATRIOVENTRICULAR BLOCK FIRST DEGREE	1 (1.2)	1	0	0	1 (1.2)	1	1 (0.6)	1
ATRIOVENTRICULAR BLOCK SECOND DEGREE	1 (1.2)	1	0	0	0	0	0	0
BRADYCARDIA	1 (1.2)	4	0	0	0	0	0	0
BUNDLE BRANCH BLOCK LEFT	1 (1.2)	1	0	0	0	0	0	0
BUNDLE BRANCH BLOCK RIGHT	1 (1.2)	2	0	0	1 (1.2)	1	1 (0.6)	1
CARDIAC DISORDER	0	0	1 (1.2)	1	0	0	1 (0.6)	1
CARDIAC FAILURE CONGESTIVE	1 (1.2)	1	0	0	0	0	0	0
MYOCARDIAL INFARCTION	4 (4.7)	4	4 (4.8)	8	2 (2.4)	4	6 (3.6)	12
PALPITATIONS	0	0	0	0	2 (2.4)	2	2 (1.2)	2
SINUS ARRHYTHMIA	1 (1.2)	2	0	0	0	0	0	0
SINUS BRADYCARDIA	2 (2.3)	2	8 (9.5)	12	7 (8.3)	10	15 (8.9)	22
SUPRAVENTRICULAR EXTRASYSTOLES	1 (1.2)	2	1 (1.2)	1	1 (1.2)	2	2 (1.2)	3
SUPRAVENTRICULAR TACHYCARDIA	0	0	0	0	1 (1.2)	2	1 (0.6)	2
TACHYCARDIA	1 (1.2)	2	0	0	0	0	0	0
VENTRICULAR EXTRASYSTOLES	0	0	1 (1.2)	1	2 (2.4)	4	3 (1.8)	5
VENTRICULAR HYPERTROPHY	1 (1.2)	1	0	0	0	0	0	0
WOLFF-PARKINSON-WHITE SYNDROME	0	0	0	0	1 (1.2)	2	1 (0.6)	2

Note: Treatment-Emergent Adverse Event is any event either reported for the first time or worsening of a pre-existing event after firstdose of study drug until 28 days after the last dose of study drug.
Note: Denominator of percentage is the number of subjects in the column.

Program: ae2.R Date Produced: 2026-11-13 Page 1 of 13

Acknowledgement for use of the data: Gautier F, Bundfuss S, Mancini E, Patil L, Rodriguez G, Shuliar V (2026). *pharmaverseadam: ADaM Test Data for the 'Pharmaverse' Family of Packages*. R package version 1.4.0, https://pharmaverse.github.io/pharmaverseadam/.

```
#Setup
library(pharmaverseadam)
library(sassy)
library(tidyverse)

options("logr.autolog" = TRUE, "logr.notes" = FALSE,
        "logr.on" = TRUE, "procs.print" = FALSE)

tmp <- tempdir()


#Setup population - need trt total col. & counts
data("adsl")
sl0 <- datastep(adsl,
                keep = v(USUBJID, ARMCD, SAFFL),
                where = expression(SAFFL == "Y"),
                {
                  output()
                  if (ARMCD != "Pbo")
                   {ARMCD <- "ZZZ"
                    output()}
                })

pop0a <- proc_freq(sl0, tables=ARMCD)
pop0 <- datastep(pop0a, keep = v(CAT, CNT),
                 rename = c(CAT="BY", CNT="BIGN"),{})

pop1 <- proc_freq(sl0, tables=ARMCD, output = long,
                  options = v(nopercent, nonobs))


#Setup AE data, create trt. and AEDECOD/AEBODSYS totals
data("adae")
ae0a <- datastep(
 adae,
 keep = v(USUBJID,ARMCD,SAFFL,TRTEMFL,AEDECOD,AEBODSYS),
 where = expression(SAFFL == "Y" & TRTEMFL == "Y"),
                {
                  output()
                  if (ARMCD != "Pbo")
                    {ARMCD <- "ZZZ"
                     output()}
                  })
ae0 <- datastep(ae0a,
                {
                  output()
                  AEDECOD <- "AAA"
                  output()
                  AEBODSYS <- "AAA"
                  output()
                })
```

```
#The counts, first number of AES, then patient count
ae1a <- proc_freq(ae0, by=ARMCD, tables=AEBODSYS*AEDECOD, options=nosparse)
ae1 <- datastep(ae1a, keep = v(BY, CAT1, CAT2, CNT),
                rename = c(CNT="INC"),{})

ae2a <- proc_sort(ae0, by=v(USUBJID, ARM, ARMCD, AEDECOD, AEBODSYS),
                  keep=v(USUBJID, ARM, ARMCD, AEDECOD, AEBODSYS),
                  options=nodupkey)
ae2b <- proc_freq(ae2a, by=ARMCD, tables=AEBODSYS*AEDECOD, options=nosparse)
ae2 <- datastep(ae2b,
                keep = v(BY, CAT1, CAT2, CNT),{})

#Merge ae and patient, then merge population, setting results
ae3a <- datastep(ae2, merge = ae1,
                merge_by = c("BY","CAT1","CAT2"),
                merge_in = c("inA", "inB"),
                where = expression(inA & inB), {})
ae3 <- datastep(ae3a, merge = pop0, merge_by = c("BY"),
                merge_in = c("inC", "inD"), where = expression(inC),
       {
         if (CNT>0)
          rslt <- str_c(sprintf("%.0f", CNT)," (",
                        sprintf("%.1f", CNT*100/BIGN),")",sep="")
         else if (CNT==0) rslt <- str_c(sprintf("%.0f", CNT),sep="")
         incd <- str_c(sprintf("%.0f", INC))
       })

ae4a <- proc_transpose(ae3, by=v(CAT1,CAT2), id=v(BY),
                       var=v(rslt), prefix=R, options=noname)
ae4b <- proc_transpose(ae3, by=v(CAT1,CAT2), id=v(BY),
                        var=v(incd), prefix=I, options=noname)
ae4 <- datastep(ae4a, merge = ae4b,
                merge_by = c("CAT1","CAT2"),
                merge_in = c("inA", "inB"),
                where = expression(inA & inB),
                {
                  if (CAT1=="AAA") {lbl1<-"Any Adverse Event"}
                  else {lbl1<-CAT1}
                  if (CAT2!="AAA") {lbl2<-CAT2}

                  if (is.na(RPbo)) {RPbo<-'0'}
                  if (is.na(IPbo)) {IPbo<-'0'}
                  if (is.na(RXan_Hi)) {RXan_Hi<-'0'}
                  if (is.na(IXan_Hi)) {IXan_Hi<-'0'}
                  if (is.na(RXan_Lo)) {RXan_Lo<-'0'}
                  if (is.na(IXan_Lo)) {IXan_Lo<-'0'}
                  if (is.na(RZZZ)) {RZZZ<-'0'}
                  if (is.na(IZZZ)) {IZZZ<-'0'}
                 })
```

The Summary Treatment Emergent Adverse Event by Body System and Preferred Term Table

Using R (SASSY, Pharmaverse and Tidyverse)

Authored by David Franklin, TheProgrammersCabin.com2026-11-13 (Page 2 of 2)

```
#Sort final data into order
final <- proc_sort(ae4, by=v(CAT1, CAT2),
                   keep=v(lbl1, lbl2, RPbo, IPbo, RXan_Hi, IXan_Hi, RXan_Lo, IXan_Lo, RZZZ, IZZZ))

#Create table
tbl <- create_table(final, first_row_blank = TRUE, width=9) |>
  column_defaults(from = 'RPbo', to = 'IZZZ', align = "center", width = 0.7) |>
  spanning_header("RPbo", "IPbo", label = "Placebo", n = pop1["Pbo"]) |>
  spanning_header("RXan_Hi", "IXan_Hi", label = "Xanomeline High Dose", n = pop1["Xan_Hi"]) |>
  spanning_header("RXan_Lo", "IXan_Lo", label = "Xanomeline Low Dose", n = pop1["Xan_Lo"]) |>
  spanning_header("RZZZ", "IZZZ", label = "All Xanomeline", n = pop1["ZZZ"]) |>
  stub(vars = c("lbl1", "lbl2"), label = "System Organ Class\n   Preferred Term", width = 3.3, align="left") |>
  define(lbl1, blank_after = TRUE) |>
  define(lbl2, indent = .25) |>
  define('RPbo', label = "n (%)") |>
  define('IPbo', label = "Events") |>
  define('RXan_Hi', label = "n (%)") |>
  define('IXan_Hi', label = "Events") |>
  define('RXan_Lo', label = "n (%)") |>
  define('IXan_Lo', label = "Events") |>
  define('RZZZ', label = "n (%)") |>
  define('IZZZ', label = "Events")

#Add titles, footnotes, headers and footers
rpt <- create_report(file.path(tmp, "ae2.pdf"),
                     output_type = "PDF", font = "Arial") |>
  page_header("Sponsor: Yum, Yum and Yum Inc.", "Study: Sweet Sauce III") |>
  set_margins(top = 1, bottom = 1) |>
  titles("Table 14.3-2",
         "Summary of Treatment-Emergent Adverse Events by Body System, Preferred Term and Treatment",
         "Safety Population", bold = TRUE, borders = "bottom") |>
  add_content(tbl) |>
  footnotes("Note: Treatment-Emergent Adverse Event is any event either reported for the first time or " %p%
            "worsening of a pre-existing event after firstdose of study drug " %p%
            "until 28 days after the last dose of study drug.",
            "Note: Denominator of percentage is the number of subjects in the column.",
            borders = "top", blank_row = "none") |>
  page_footer("Program: ae2.R   Date Produced: {Sys.Date()}", right = "Page [pg] of [tpg]")

#Output report
res <- write_report(rpt)

#Close log
log_close()
```

