

safetyData: Join SDTM.DS with SUPPDS

Noory Kim

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```
library(safetyData) # a package with sample CDISC data sets
library(tidyverse)

## Get list of datasets
dataset_list <- data(package = "safetyData")$results[, "Item"]
dataset_list[1:5]

## [1] "adam_adae"      "adam_adlbc"      "adam_adlbh"      "adam_adlbhy"
## [5] "adam_adqsadas"
```

A. Transpose SUPPDS

```
sdtm_suppds[c(1:2), c(3:8)]

##           USUBJID IDVAR IDVARVAL      QNAM              QLABEL QVAL
## 1 01-703-1175 DSSEQ           1 ENTCRIT PROTOCOL ENTRY CRITERIA NOT MET    16
## 2 01-705-1382 DSSEQ           1 ENTCRIT PROTOCOL ENTRY CRITERIA NOT MET    25
```

Transpose and drop columns not needed for ADaMs or TLFs:

NOTES:

- pivot_wider() « tidyr
 - column names are case sensitive
- select() « dplyr

```
cols_to_drop <- c("STUDYID", "RDOMAIN", "IDVAR", "QLABEL", "QORIG", "QEVAL")

sdtm_suppds_t <- sdtm_suppds %>%
  pivot_wider(names_from=QNAM, values_from=QVAL) %>%
  select(-all_of(cols_to_drop))
dim(sdtm_suppds_t)
```

```
## [1] 3 3
```

```
sdtm_suppds_t[c(1:3),]
```

```
## # A tibble: 3 x 3
##   USUBJID      IDVARVAL ENTCRIT
##   <chr>         <int>   <int>
## 1 01-703-1175         1       16
## 2 01-705-1382         1       25
## 3 01-708-1372         1       16
```

B. Join DS with transposed SUPPDS

```
ds001 <- sdtm_ds
dim(ds001)
```

```
## [1] 596 13
```

```
ds001[c(1:3), ]
```

```
##          STUDYID DOMAIN      USUBJID DSSEQ DSSPID          DSTERM
## 1 CDISCPIL0T01      DS 01-701-1015      1      NA PROTOCOL COMPLETED
## 2 CDISCPIL0T01      DS 01-701-1015      2      NA      FINAL LAB VISIT
## 3 CDISCPIL0T01      DS 01-701-1023      1      24      ADVERSE EVENT
##          DSDECOD          DSCAT VISITNUM  VISIT          DSDTC
## 1      COMPLETED DISPOSITION EVENT      13 WEEK 26      2014-07-02
## 2 FINAL LAB VISIT      OTHER EVENT      13 WEEK 26 2014-07-02T11:45
## 3  ADVERSE EVENT DISPOSITION EVENT      5  WEEK 4      2012-09-02
##          DSSTDTC DSSTDY
## 1 2014-07-02      182
## 2 2014-07-02      182
## 3 2012-09-02      29
```

```
ds002 <- left_join(ds001, sdtm_suppds_t, by=c("USUBJID"="USUBJID", "DSSEQ"="IDVARVAL"))
dim(ds002)
```

```
## [1] 596 14
```

Check results: See rows where SUPPDS.ENTCRIT is not missing

```
ds002_q1 <- ds002 %>%
  filter(!is.na(ENTCRIT))
dim(ds002_q1)
```

```
## [1] 3 14
```

```
head(ds002_q1)
```

```
##          STUDYID DOMAIN      USUBJID DSSEQ DSSPID          DSTERM
## 1 CDISCPIL0T01      DS 01-703-1175      1      NA PROTOCOL ENTRY CRITERIA NOT MET
## 2 CDISCPIL0T01      DS 01-705-1382      1      NA PROTOCOL ENTRY CRITERIA NOT MET
## 3 CDISCPIL0T01      DS 01-708-1372      1      NA PROTOCOL ENTRY CRITERIA NOT MET
##          DSDECOD          DSCAT VISITNUM  VISIT          DSDTC      DSSTDTC
## 1 PROTOCOL VIOLATION DISPOSITION EVENT      4 WEEK 2 2013-12-31 2013-12-31
## 2 PROTOCOL VIOLATION DISPOSITION EVENT      4 WEEK 2 2013-05-13 2013-05-13
## 3 PROTOCOL VIOLATION DISPOSITION EVENT      4 WEEK 2 2013-05-10 2013-05-10
##          DSSTDY ENTCRIT
## 1      12      16
## 2       1      25
## 3      29      16
```