TLG-cat-saftey-summary-tbl.R

Admin

2024-10-23

```
# Saftey summary
library(tern)
```

```
## Loading required package: rtables
```

```
## Loading required package: formatters
```

```
##
## Attaching package: 'formatters'
```

```
## The following object is masked from 'package:base':
##
##     %||%
```

```
## Loading required package: magrittr
```

```
##
## Attaching package: 'rtables'
```

```
## The following object is masked from 'package:utils':
##
##     str
```

```
## Registered S3 method overwritten by 'tern':
##   method   from
##   tidy.glm broom
```

```
library(dplyr)
```

```
##
## Attaching package: 'dplyr'
```

```
## The following objects are masked from 'package:stats':
##
##     filter, lag
```

```
## The following objects are masked from 'package:base':
##
##     intersect, setdiff, setequal, union
```

```
adsl <- random.cdisc.data::cadsl
adae <- random.cdisc.data::cadae

# Ensure character variables are converted to factors and empty strings and NAs are explicit
missing levels.
adsl <- df_explicit_na(adsl)
adae <- df_explicit_na(
  adae,
  omit_columns = c("SMQ01NAM", "SMQ01SC", "SMQ02NAM", "SMQ02SC", "CQ01NAM", "STUDYID", "USUBJ
ID")
)

set.seed(99)

adae <- adae %>%
  mutate(
    AEDECOD = with_label(as.character(AEDECOD), "Dictionary-Derived Term"),
    AESDTH = with_label(
      sample(c("N", "Y"), size = nrow(adae), replace = TRUE, prob = c(0.99, 0.01)),
      "Results in Death"
    ),
    AEACN = with_label(
      sample(
        c("DOSE NOT CHANGED", "DOSE INCREASED", "DRUG INTERRUPTED", "DRUG WITHDRAWN"),
        size = nrow(adae),
        replace = TRUE, prob = c(0.68, 0.02, 0.25, 0.05)
      ),
      "Action Taken with Study Treatment"
    ),
    FATAL = with_label(AESDTH == "Y", "AE with fatal outcome"),
    SEV = with_label(AESEV == "SEVERE", "Severe AE (at greatest intensity)"),
    SER = with_label(AESER == "Y", "Serious AE"),
    SERWD = with_label(AESER == "Y" & AEACN == "DRUG WITHDRAWN", "Serious AE leading to withd
rawal from treatment"),
    SERDSM = with_label(
      AESER == "Y" & AEACN %in% c("DRUG INTERRUPTED", "DOSE INCREASED", "DOSE REDUCED"),
      "Serious AE leading to dose modification/interruption"
    ),
    RELSER = with_label(AESER == "Y" & AEREL == "Y", "Related Serious AE"),
    WD = with_label(AEACN == "DRUG WITHDRAWN", "AE leading to withdrawal from treatment"),
    DSM = with_label(
      AEACN %in% c("DRUG INTERRUPTED", "DOSE INCREASED", "DOSE REDUCED"), "AE leading to dose
modification/interruption"
    ),
    REL = with_label(AEREL == "Y", "Related AE"),
    RELWD = with_label(AEREL == "Y" & AEACN == "DRUG WITHDRAWN", "Related AE leading to withd
rawal from treatment"),
    RELDSM = with_label(
      AEREL == "Y" & AEACN %in% c("DRUG INTERRUPTED", "DOSE INCREASED", "DOSE REDUCED"),
      "Related AE leading to dose modification/interruption"
    ),
    CTC35 = with_label(AETOXGR %in% c("3", "4", "5"), "Grade 3-5 AE"),
    CTC45 = with_label(AETOXGR %in% c("4", "5"), "Grade 4/5 AE"),
    SMQ01 = with_label(SMQ01NAM != "", aesi_label(adae$SMQ01NAM, adae$SMQ01SC)),
    SMQ02 = with_label(SMQ02NAM != "", aesi_label(adae$SMQ02NAM, adae$SMQ02SC)),
```

```
    CQ01 = with_label(CQ01NAM != "", aesi_label(adae$CQ01NAM)),
    USUBJID_AESEQ = paste(USUBJID, AESEQ, sep = "@@") # Create unique ID per AE in dataset.
  ) %>%
  filter(ANL01FL == "Y")

aesi_vars <- c("FATAL", "SER", "SERWD", "SERDSM", "RELSER", "WD", "DSM", "REL", "RELWD", "REL
DSM", "SEV")

# Layout for variables from adsl dataset.
lyt_adsl <- basic_table(show_colcounts = TRUE) %>%
  split_cols_by("ACTARM") %>%
  count_patients_with_event(
    "USUBJID",
    filters = c("DTHFL" = "Y"),
    denom = "N_col",
    .labels = c(count_fraction = "Total number of deaths")
  ) %>%
  count_patients_with_event(
    "USUBJID",
    filters = c("DCSREAS" = "ADVERSE EVENT"),
    denom = "N_col",
    .labels = c(count_fraction = "Total number of patients withdrawn from study due to an A
E"),
    table_names = "tot_wd"
  )

result_adsl <- build_table(lyt_adsl, df = adsl, alt_counts_df = adsl)

# Layout for variables from adae dataset.
lyt_adae <- basic_table(show_colcounts = TRUE) %>%
  split_cols_by("ACTARM") %>%
  analyze_num_patients(
    vars = "USUBJID",
    .stats = c("unique", "nonunique"),
    .labels = c(
      unique = "Total number of patients with at least one AE",
      nonunique = "Total number of AEs"
    ),
    .formats = list(unique = format_count_fraction_fixed_dp, nonunique = "xx"),
    show_labels = "hidden"
  ) %>%
  count_patients_with_flags(
    "USUBJID",
    flag_variables = aesi_vars,
    denom = "N_col",
    var_labels = "Total number of patients with at least one",
    show_labels = "visible"
  )

result_adae <- build_table(lyt_adae, df = adae, alt_counts_df = adsl)

# Combine tables.
col_info(result_adsl) <- col_info(result_adae)
result <- rbind(
  result_adae[1:2, ],
  result_adsl,
```

```
  result_adae[3:nrow(result_adae), ]
)

result
```

```
##                                                          A: Drug X    B: Placebo   C:
Combination
##                                                           (N=134)      (N=134)
(N=132)
##
-------------------------------------------------------------------------------------
---------
## Total number of patients with at least one AE          100 (74.6%)   98 (73.1%)    1
03 (78.0%)
## Total number of AEs                                        502          480
604
## Total number of deaths                                 25 (18.7%)    23 (17.2%)
22 (16.7%)
## Total number of patients withdrawn from study due to an AE  3 (2.2%)      6 (4.5%)
5 (3.8%)
## Total number of patients with at least one
##   AE with fatal outcome                                 5 (3.7%)      5 (3.7%)
6 (4.5%)
##   Serious AE                                           85 (63.4%)    80 (59.7%)
87 (65.9%)
##   Serious AE leading to withdrawal from treatment       6 (4.5%)     12 (9.0%)
9 (6.8%)
##   Serious AE leading to dose modification/interruption 36 (26.9%)    40 (29.9%)
47 (35.6%)
##   Related Serious AE                                   64 (47.8%)    52 (38.8%)
64 (48.5%)
##   AE leading to withdrawal from treatment              20 (14.9%)    24 (17.9%)
26 (19.7%)
##   AE leading to dose modification/interruption         63 (47.0%)    70 (52.2%)
77 (58.3%)
##   Related AE                                           86 (64.2%)    85 (63.4%)
92 (69.7%)
##   Related AE leading to withdrawal from treatment      10 (7.5%)      9 (6.7%)
12 (9.1%)
##   Related AE leading to dose modification/interruption 44 (32.8%)    44 (32.8%)
51 (38.6%)
##   Severe AE (at greatest intensity)                    77 (57.5%)    70 (52.2%)
79 (59.8%)
```