# Creating a basic data structure (BDS) Exposure ADaM

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## Programming workflow



Get required R packages

```
Warning: package 'pharmaversesdtm' was built under R version 4.4.2
```

```
Attaching package: 'lubridate'
```

```
The following objects are masked from 'package:base':

    date, intersect, setdiff, union
```

## Read CDISC pilot SDTM and ADaM datasets

```
adsl_vars <- exprs(TRTSDT, TRTSDTM, TRTEDT, TRTEDTM)

# left join EX and adsl TRTSDT, TRTSDTM, TRTEDT, TRTEDTM on ex.STUDYID=adslSTUDYID and ex.USUB
adex <- derive_vars_merged(
   dataset=ex
  ,dataset_add = adsl
  ,new_vars = adsl_vars
  ,by_vars = exprs(STUDYID, USUBJID)
  ) # dim(adex) 591 21
```

The CDISC pilot EX domain data does not contain a dose adjustment flag or the planned dose information. For demonstration purposes, this will be added to the data.

### EXADJ

- Exposure Adjustment ?

### EXDOSE

- exposure dose
- from SDTM.EX.EXDOSE

### EXPLDOS

- Planned Dose

```
adex <- adex %>%
  mutate(
    EXADJ = case_when(
      USUBJID == "01-701-1028" & VISIT %in% c("WEEK 2") ~ "ADVERSE EVENT",
      USUBJID == "01-701-1148" & VISIT %in% c("WEEK 2", "WEEK 24") ~ "MEDICATION ERROR",
      TRUE ~ NA_character_
    ),
    EXDOSE = case_when(
      USUBJID == "01-701-1028" & VISIT %in% c("WEEK 2") ~ 0,
      USUBJID == "01-701-1148" & VISIT %in% c("WEEK 2", "WEEK 24") ~ 0,
      TRUE ~ EXDOSE
    )
  ) %>%
  mutate(EXPLDOS = if_else(EXTRT == "PLACEBO", 0, 54))

adex %>% select(EXTRT, EXPLDOS) %>% distinct()
```

```
# A tibble: 2 x 2
  EXTRT      EXPLDOS
  <chr>        <dbl>
1 PLACEBO          0
2 XANOMELINE      54
```

## Derive numeric datetime, analysis day variables

### ASTDT

- Analysis Start Date
- Set to a numeric form of EX.EXSTDTC when EX.EXSTDTC consists of a full date.

### AENDT

- Analysis End Date
- Set to a numeric form of EX.EXENDTC when EX.EXENDTC consists of a full date.

```
# Convert character datetime to numeric datetime
adex <- derive_vars_dt(adex, new_vars_prefix = "AST", dtc = EXSTDTC)
adex <- derive_vars_dt(adex, new_vars_prefix = "AEN", dtc = EXENDTC) # dim(adex) 591 25
adex %>% select(USUBJID,VISIT,EXSTDTC,EXENDTC,ASTDT,AENDT) %>% head()
```

```
# A tibble: 6 x 6
  USUBJID     VISIT    EXSTDTC    EXENDTC    ASTDT      AENDT
  <chr>       <chr>    <chr>      <chr>      <date>     <date>
1 01-701-1015 BASELINE 2014-01-02 2014-01-16 2014-01-02 2014-01-16
2 01-701-1015 WEEK 2   2014-01-17 2014-06-18 2014-01-17 2014-06-18
3 01-701-1015 WEEK 24  2014-06-19 2014-07-02 2014-06-19 2014-07-02
4 01-701-1023 BASELINE 2012-08-05 2012-08-27 2012-08-05 2012-08-27
5 01-701-1023 WEEK 2   2012-08-28 2012-09-01 2012-08-28 2012-09-01
6 01-701-1028 BASELINE 2013-07-19 2013-08-01 2013-07-19 2013-08-01
```

### ASTDTM

### AENDTM

The next examples demonstrates the datetime imputation features available in the `derive_vars_dtm()` function, where the time is imputed as “00:00:00”:

```
adex <- derive_vars_dtm(
  adex
  ,dtc = EXSTDTC
  # Impute dtc date to the first day of the month
  ,highest_imputation = "M"
  ,date_imputation = "first"
  ,new_vars_prefix = "AST"
)

adex <- derive_vars_dtm(
  adex,
  dtc = EXENDTC,
  # Impute dtc date to the last day of the month
  highest_imputation = "M",
  date_imputation = "last",
  new_vars_prefix = "AEN"
)

adex %>% select(EXSTDTC,EXENDTC,ASTDTM,AENDTM) %>% head()
```

```
# A tibble: 6 x 4
  EXSTDTC    EXENDTC    ASTDTM              AENDTM
  <chr>      <chr>      <dttm>              <dttm>
1 2014-01-02 2014-01-16 2014-01-02 00:00:00 2014-01-16 00:00:00
2 2014-01-17 2014-06-18 2014-01-17 00:00:00 2014-06-18 00:00:00
3 2014-06-19 2014-07-02 2014-06-19 00:00:00 2014-07-02 00:00:00
4 2012-08-05 2012-08-27 2012-08-05 00:00:00 2012-08-27 00:00:00
5 2012-08-28 2012-09-01 2012-08-28 00:00:00 2012-09-01 00:00:00
6 2013-07-19 2013-08-01 2013-07-19 00:00:00 2013-08-01 00:00:00
```

### ASTDY

- Analysis Start Day
- ‘ASTDT-TRTSDT+1‘

### AENDY

- Analysis End Day
- ‘AENDT-TRTSDT+1‘

```
adex <- derive_vars_dy(
  dataset=adex
  ,reference_date = TRTSDT
  ,source_vars = exprs(ASTDT, AENDT)
```

```
  ) # dim(adex) 591 33
adex %>% select(TRTSDT, ASTDT, ASTDY, AENDT, AENDY) %>% head()
```

```
# A tibble: 6 x 5
  TRTSDT     ASTDT      ASTDY AENDT      AENDY
  <date>     <date>     <dbl> <date>     <dbl>
1 2014-01-02 2014-01-02     1 2014-01-16    15
2 2014-01-02 2014-01-17    16 2014-06-18   168
3 2014-01-02 2014-06-19   169 2014-07-02   182
4 2012-08-05 2012-08-05     1 2012-08-27    23
5 2012-08-05 2012-08-28    24 2012-09-01    28
6 2013-07-19 2013-07-19     1 2013-08-01    14
```

## EXDURD

- Duration of treatment or exposure
- 'EXDURD=AENDT - ASTDT +1'

```
adex <- adex %>%
  derive_vars_duration(
    new_var = EXDURD
    ,start_date = ASTDT
    ,end_date = AENDT
    # duration unit can be "years", "months", "weeks", "days", "hours", "minutes", "seconds"
    ,out_unit = "DAYS")

adex %>% select(ASTDT, AENDT, EXDURD) %>% head()
```

```
# A tibble: 6 x 3
  ASTDT      AENDT      EXDURD
  <date>     <date>      <dbl>
1 2014-01-02 2014-01-16     15
2 2014-01-17 2014-06-18    153
3 2014-06-19 2014-07-02     14
4 2012-08-05 2012-08-27     23
5 2012-08-28 2012-09-01      5
6 2013-07-19 2013-08-01     14
```

## DOSEO

- EXDOSE * EXDURD

### PDOSEO

- 'EXPLDOS * EXDURD'

```
adex <- adex %>%
  mutate(
    DOSEO = EXDOSE * EXDURD
    ,PDOSEO = EXPLDOS * EXDURD)

adex %>% select(USUBJID, EXDOSE, EXPLDOS, EXDURD, DOSEO, PDOSEO) %>% head()
```

```
# A tibble: 6 x 6
  USUBJID     EXDOSE EXPLDOS EXDURD DOSEO PDOSEO
  <chr>        <dbl>   <dbl>  <dbl> <dbl>  <dbl>
1 01-701-1015      0       0     15     0      0
2 01-701-1015      0       0    153     0      0
3 01-701-1015      0       0     14     0      0
4 01-701-1023      0       0     23     0      0
5 01-701-1023      0       0      5     0      0
6 01-701-1028     54      54     14   756    756
```

## References


Creating a BDS Exposure ADaM

ADaM Subject-level Analysis - ADSL Dataset