Mini ADSL R program

December 25, 2025

0.1 Mini ADSL R program

[ ]:
```
######    General Packages
install.packages("pacman")        # p_load(dplyr, ggplot2, readr)  # installs␣
 ↪any missing, then loads all
```

[29]:
```
################
pacman::p_load(haven, dplyr,tidyr, purrr, glue, lubridate,stringr, EDCimport)
```

Upload the following SDTM datasets/exports needed to program ADAM.ADSL:

[7]:
```
dm          <-   read_xpt("DM.xpt")
suppdm      <-   read_xpt("SUPPDM.xpt")
ds          <-   read_xpt("DS.xpt")
vs          <-   read_xpt("VS.xpt")
```

Merge DM and SUPPDM: Transponse SUPPDM data such that each QNAM becomes a variable

[9]:
```
suppdmtrp <- suppdm %>%
    mutate(qnam=str_to_lower(qnam)) %>%
    group_by(studyid, usubjid) %>%
    pivot_wider(id_cols=c(studyid,usubjid),names_from = qnam, values_from =␣
 ↪qval)
suppdmtrp
```

A grouped_df: 2 × 5

studyid <chr>	usubjid <chr>	race1 <chr>	race2 <chr>	racesp <chr>
STU001	STU001-1002	ASIAN	AMERICAN INDIAN OR ALASKA NATIVE	NA
STU001	STU001-1003	NA	NA	BRAZ

[10]:
```
all_dm <- left_join(dm, suppdmtrp, by = c("studyid", "usubjid"))
```

[11]:
```
all_dm
```

A tibble: 8 × 26

studyid <chr>	domain <chr>	usubjid <chr>	subjid <chr>	rfstdtc <chr>	rfendtc <chr>	rfxstdtc <chr>	rfxe <ch
STU001	DM	STU001-1001	1001	2010-01-01			
STU001	DM	STU001-1002	1002	2010-01-01	2010-01-05		
STU001	DM	STU001-1003	1003	2010-01-03	2010-01-05		
STU001	DM	STU001-1004	1004	2010-01-05	2010-02-28	2010-01-05T08:35	2010
STU001	DM	STU001-1005	1005	2010-02-05		2010-02-05T08:46	2010
STU001	DM	STU001-1006	1006	2010-03-02	2010-03-25	2010-03-02T08:30	2010
STU001	DM	STU001-1007	1007	2010-04-15	2010-06-12	2010-04-15T08:23	2010
STU001	DM	STU001-1008	1008	2010-06-27	2010-08-18	2010-06-27T08:45	2010

Create variables that are directly based on input variables: trt01p trt01a trt01pn trt01an tr01sdt tr01edt rficdt lstalvdt dthdt trtsdt trtedt agegr1 agegr1n

[14]:
```
trtdata <- all_dm %>%

   mutate(trt01p =  if_else(armcd == "PBO", "Placebo", if_else(armcd ==␣
↪"ACTIVE", "Active", "")),
      trt01a =  if_else(actarmcd == "PBO", "Placebo", if_else(actarmcd ==␣
↪"ACTIVE", "Active", "")),
      trt01pn = if_else(armcd == "PBO", 1, if_else(armcd == "ACTIVE", 2, NA)),
      trt01an = if_else(actarmcd == "PBO", 1, if_else(actarmcd == "ACTIVE", 2,␣
↪NA))) %>%

   mutate(tr01sdt = as.Date(rfxstdtc),
      tr01edt = as.Date(rfxendtc),
      rficdt = as.Date(rficdtc),
      lstalvdt = as.Date(rfpendtc),
      dthdt = as.Date(dthdtc),
      trtsdt = tr01sdt,
      trtedt = tr01edt) %>%

   mutate(agegr1 = if_else(!is.na(age) & age < 60, "< 60 Years",
      if_else(age >= 60, ">= 60 Years", "")),
      agegr1n = if_else(!is.na(age) & age < 60, 1, if_else(age >= 60, 2,NA)))

select(trtdata, c('usubjid', 'trt01p','trt01a','trt01pn',␣
↪'trt01an','agegr1','agegr1n', 'ethnic'))
```

A tibble: 8 × 8

usubjid <chr>	trt01p <chr>	trt01a <chr>	trt01pn <dbl>	trt01an <dbl>	agegr1 <chr>	agegr1n <dbl>	ethnic <chr>
STU001-1001			NA	NA	< 60 Years	1	HISPANIC OR
STU001-1002			NA	NA	< 60 Years	1	NOT HISPAN
STU001-1003	Placebo		1	NA	< 60 Years	1	HISPANIC OR
STU001-1004	Active	Active	2	2	< 60 Years	1	HISPANIC OR
STU001-1005	Active	Placebo	2	1	>= 60 Years	2	NOT HISPAN
STU001-1006	Placebo	Placebo	1	1	>= 60 Years	2	NOT HISPAN
STU001-1007	Placebo	Placebo	1	1	< 60 Years	1	NOT HISPAN
STU001-1008	Active	Active	2	2	>= 60 Years	2	NOT HISPAN

Process disposition data for treatment and study status enrldt randdt eotstt dctreas ineot

[15]:
```
enrldate <- ds %>%
        filter(dsterm == "ENROLLED") %>%
        mutate(enrldt = as.Date(dsstdtc)) %>%
        select(studyid, usubjid, enrldt)
enrldate
```

A tibble: 7 × 3

studyid <chr>	usubjid <chr>	enrldt <date>
STU001	STU001-1002	2010-01-04
STU001	STU001-1003	2010-01-03
STU001	STU001-1004	2010-01-04
STU001	STU001-1005	2010-02-01
STU001	STU001-1006	2010-03-01
STU001	STU001-1007	2010-04-14
STU001	STU001-1008	2010-06-26

[16]:
```
randdate <- ds %>%
    filter(dsterm == "RANDOMIZED") %>%
    mutate(randdt = as.Date(dsstdtc)) %>%
    select(studyid, usubjid, randdt)

randdate
```

A tibble: 6 × 3

studyid <chr>	usubjid <chr>	randdt <date>
STU001	STU001-1003	2010-01-03
STU001	STU001-1004	2010-01-05
STU001	STU001-1005	2010-02-05
STU001	STU001-1006	2010-03-01
STU001	STU001-1007	2010-04-14
STU001	STU001-1008	2010-06-27

[17]:
```
eotdata <- ds %>%
     filter(dsscat == "END OF TREATMENT") %>%
     mutate(
     eotstt = case_when(
     dsdecod == "COMPLETED" ~ "COMPLETED",
     dsdecod != "" ~ "DISCONTINUED",
     TRUE ~ NA
     ),
     dctreas = if_else(dsdecod != "COMPLETED", dsdecod, NA),
     ineot = 1
 ) %>%
 select(studyid, usubjid, eotstt, dctreas, ineot)

eotdata
```

A tibble: 4 × 5

studyid <chr>	usubjid <chr>	eotstt <chr>	dctreas <chr>	ineot <dbl>
STU001	STU001-1004	COMPLETED	NA	1
STU001	STU001-1006	DISCONTINUED	ADVERSE EVENT	1
STU001	STU001-1007	COMPLETED	NA	1
STU001	STU001-1008	DISCONTINUED	SUBJECT REQUEST	1

[18]:
```
eosdata <- ds %>%
     filter(dsscat == "END OF STUDY") %>%
     mutate(
     eosstt = case_when(
     dsdecod == "COMPLETED" ~ "COMPLETED",
     dsdecod != "" ~ "DISCONTINUED",
     TRUE ~ NA
 ),
     dcsreas = if_else(dsdecod != "COMPLETED", dsdecod, NA),
     eosdt = as.Date(dsstdtc),
     ineos = 1
 ) %>%
 select(studyid, usubjid, eosstt, dcsreas, eosdt, ineos)
 eosdata
```

A tibble: 6 × 6

studyid <chr>	usubjid <chr>	eosstt <chr>	dcsreas <chr>	eosdt <date>	ine <d
STU001	STU001-1002	DISCONTINUED	WITHDRAWL OF CONSENT	2010-01-05	1
STU001	STU001-1003	DISCONTINUED	DEATH	2010-01-05	1
STU001	STU001-1004	COMPLETED	NA	2010-02-28	1
STU001	STU001-1006	DISCONTINUED	ADVERSE EVENT	2010-03-25	1
STU001	STU001-1007	COMPLETED	NA	2010-06-12	1
STU001	STU001-1008	DISCONTINUED	SUBJECT REQUEST	2010-08-18	1

Baseline variables from vital signs; heightbl weightbl

[19]:
```
heightbl <- vs %>%
     filter(vsblfl == "Y" & vstestcd == "HEIGHT") %>%
     select(studyid, usubjid, vsstresn) %>%
     rename(heightbl = vsstresn)
heightbl

weightbl <- vs %>%
     filter(vsblfl == "Y" & vstestcd == "WEIGHT") %>%
     select(studyid, usubjid, vsstresn) %>%
     rename(weightbl = vsstresn)
weightbl
```

A tibble: 4 × 3

studyid <chr>	usubjid <chr>	heightbl <dbl>
STU001	STU001-1004	177.00
STU001	STU001-1005	66.14
STU001	STU001-1006	160.00
STU001	STU001-1007	178.00

A tibble: 4 × 3

studyid <chr>	usubjid <chr>	weightbl <dbl>
STU001	STU001-1004	87.3
STU001	STU001-1005	76.1
STU001	STU001-1006	60.9
STU001	STU001-1007	85.4

Merge all the information in created dataset

[20]:
```
all_dframes <- list(trtdata, enrldate, randdate, eotdata, eosdata, heightbl,␣
↪weightbl)
all_dframes
```

1. A tibble: 8 × 39

studyid <chr>	domain <chr>	usubjid <chr>	subjid <chr>	rfstdtc <chr>	rfendtc <chr>	rfxstdtc <chr>
STU001	DM	STU001-1001	1001	2010-01-01		
STU001	DM	STU001-1002	1002	2010-01-01	2010-01-05	
STU001	DM	STU001-1003	1003	2010-01-03	2010-01-05	
STU001	DM	STU001-1004	1004	2010-01-05	2010-02-28	2010-01-05T08:35
STU001	DM	STU001-1005	1005	2010-02-05		2010-02-05T08:46
STU001	DM	STU001-1006	1006	2010-03-02	2010-03-25	2010-03-02T08:30
STU001	DM	STU001-1007	1007	2010-04-15	2010-06-12	2010-04-15T08:23
STU001	DM	STU001-1008	1008	2010-06-27	2010-08-18	2010-06-27T08:45

2. A tibble: 7 × 3

studyid <chr>	usubjid <chr>	enrldt <date>
STU001	STU001-1002	2010-01-04
STU001	STU001-1003	2010-01-03
STU001	STU001-1004	2010-01-04
STU001	STU001-1005	2010-02-01
STU001	STU001-1006	2010-03-01
STU001	STU001-1007	2010-04-14
STU001	STU001-1008	2010-06-26

3. A tibble: 6 × 3

studyid <chr>	usubjid <chr>	randdt <date>
STU001	STU001-1003	2010-01-03
STU001	STU001-1004	2010-01-05
STU001	STU001-1005	2010-02-05
STU001	STU001-1006	2010-03-01
STU001	STU001-1007	2010-04-14
STU001	STU001-1008	2010-06-27

4. A tibble: 4 × 5

studyid <chr>	usubjid <chr>	eotstt <chr>	dctreas <chr>	ineot <dbl>
STU001	STU001-1004	COMPLETED	NA	1
STU001	STU001-1006	DISCONTINUED	ADVERSE EVENT	1
STU001	STU001-1007	COMPLETED	NA	1
STU001	STU001-1008	DISCONTINUED	SUBJECT REQUEST	1

5. A tibble: 6 × 6

studyid <chr>	usubjid <chr>	eosstt <chr>	dcsreas <chr>	eosdt <date>
STU001	STU001-1002	DISCONTINUED	WITHDRAWL OF CONSENT	2010-01-05
STU001	STU001-1003	DISCONTINUED	DEATH	2010-01-05
STU001	STU001-1004	COMPLETED	NA	2010-02-28
STU001	STU001-1006	DISCONTINUED	ADVERSE EVENT	2010-03-25
STU001	STU001-1007	COMPLETED	NA	2010-06-12
STU001	STU001-1008	DISCONTINUED	SUBJECT REQUEST	2010-08-18

6. A tibble: 4 × 3

studyid <chr>	usubjid <chr>	heightbl <dbl>
STU001	STU001-1004	177.00
STU001	STU001-1005	66.14
STU001	STU001-1006	160.00
STU001	STU001-1007	178.00

7. A tibble: 4 × 3

studyid <chr>	usubjid <chr>	weightbl <dbl>
STU001	STU001-1004	87.3
STU001	STU001-1005	76.1
STU001	STU001-1006	60.9
STU001	STU001-1007	85.4

[21]:
```
adsltemp1 <- reduce(all_dframes, left_join, by = c("studyid", "usubjid"))
adsltemp1
```

A tibble: 8 × 50

studyid <chr>	domain <chr>	usubjid <chr>	subjid <chr>	rfstdtc <chr>	rfendtc <chr>	rfxstdtc <chr>	rfxe <ch
STU001	DM	STU001-1001	1001	2010-01-01			
STU001	DM	STU001-1002	1002	2010-01-01	2010-01-05		
STU001	DM	STU001-1003	1003	2010-01-03	2010-01-05		
STU001	DM	STU001-1004	1004	2010-01-05	2010-02-28	2010-01-05T08:35	2010
STU001	DM	STU001-1005	1005	2010-02-05		2010-02-05T08:46	2010
STU001	DM	STU001-1006	1006	2010-03-02	2010-03-25	2010-03-02T08:30	2010
STU001	DM	STU001-1007	1007	2010-04-15	2010-06-12	2010-04-15T08:23	2010
STU001	DM	STU001-1008	1008	2010-06-27	2010-08-18	2010-06-27T08:45	2010

Create variables/assign values to existing variables which are dependent on their variables; saffl randfl enrlfl complfl eotstt eosstt trtdurd

[22]:
```
adsltemp2 <- adsltemp1 %>%
    mutate(
        saffl = if_else(!is.na(trtsdt), "Y", "N"),
```

```
        randfl = if_else(!is.na(randdt), "Y", "N"),
        enrlfl = if_else(!is.na(enrldt), "Y", "N"),
        complfl = if_else(eosstt == "COMPLETED", "Y", "N"),

        eotstt = if_else((eotstt == "" | is.na(eotstt))  & is.na(ineot) &␣
↪saffl == "Y", "ONGOING", eotstt),
        eosstt = if_else((eosstt == "" | is.na(eosstt)) & is.na(ineos) & saffl␣
↪== "Y", "ONGOING", eosstt),
        trtdurd = if_else(!is.na(trtsdt) & !is.na(trtedt), trtedt - trtsdt +␣
↪1, NA),
        trtdurd = as.numeric(trtdurd)
)

adsltemp2
```

A tibble: 8 × 55

studyid <chr>	domain <chr>	usubjid <chr>	subjid <chr>	rfstdtc <chr>	rfendtc <chr>	rfxstdtc <chr>	rfxe <ch
STU001	DM	STU001-1001	1001	2010-01-01			
STU001	DM	STU001-1002	1002	2010-01-01	2010-01-05		
STU001	DM	STU001-1003	1003	2010-01-03	2010-01-05		
STU001	DM	STU001-1004	1004	2010-01-05	2010-02-28	2010-01-05T08:35	2010
STU001	DM	STU001-1005	1005	2010-02-05		2010-02-05T08:46	2010
STU001	DM	STU001-1006	1006	2010-03-02	2010-03-25	2010-03-02T08:30	2010
STU001	DM	STU001-1007	1007	2010-04-15	2010-06-12	2010-04-15T08:23	2010
STU001	DM	STU001-1008	1008	2010-06-27	2010-08-18	2010-06-27T08:45	2010

Replace NA with missing

[23]:
```
adsltemp3 <- adsltemp2 %>%
    mutate(across(where(is.character), ~if_else(is.na(.), "", .)))

adsltemp3
```

A tibble: 8 × 55

studyid <chr>	domain <chr>	usubjid <chr>	subjid <chr>	rfstdtc <chr>	rfendtc <chr>	rfxstdtc <chr>	rfxe <ch
STU001	DM	STU001-1001	1001	2010-01-01			
STU001	DM	STU001-1002	1002	2010-01-01	2010-01-05		
STU001	DM	STU001-1003	1003	2010-01-03	2010-01-05		
STU001	DM	STU001-1004	1004	2010-01-05	2010-02-28	2010-01-05T08:35	2010
STU001	DM	STU001-1005	1005	2010-02-05		2010-02-05T08:46	2010
STU001	DM	STU001-1006	1006	2010-03-02	2010-03-25	2010-03-02T08:30	2010
STU001	DM	STU001-1007	1007	2010-04-15	2010-06-12	2010-04-15T08:23	2010
STU001	DM	STU001-1008	1008	2010-06-27	2010-08-18	2010-06-27T08:45	2010

[ ]:

[24]:

```
varlist <- c("STUDYID", "USUBJID", "SUBJID", "SITEID", "AGE", "AGEU", "AGEGR1",␣
 ↪"AGEGR1N", "SEX", "RACE", "RACE1", "RACE2", "RACESP", "SAFFL", "COMPLFL",␣
 ↪"RANDFL", "ENRLFL", "ARM", "ACTARM", "TRT01P", "TRT01PN", "TRT01A",␣
 ↪"TRT01AN", "TRTSDT", "TRTEDT", "TR01SDT", "TR01EDT", "EOSSTT", "EOSDT",␣
 ↪"DCSREAS", "EOTSTT", "DCTREAS", "RFICDT", "ENRLDT", "RANDDT", "LSTALVDT",␣
 ↪"TRTDURD", "DTHDT", "HEIGHTBL", "WEIGHTBL")

adsl <- adsltemp3 %>%
 rename_all(toupper) %>%
 select(all_of(varlist))

adsl
```

A tibble: 8 × 40

STUDYID <chr>	USUBJID <chr>	SUBJID <chr>	SITEID <chr>	AGE <dbl>	AGEU <chr>	AGEGR1 <chr>	AGEGR1N <dbl>
STU001	STU001-1001	1001	10	35	YEARS	< 60 Years	1
STU001	STU001-1002	1002	10	40	YEARS	< 60 Years	1
STU001	STU001-1003	1003	10	40	YEARS	< 60 Years	1
STU001	STU001-1004	1004	10	38	YEARS	< 60 Years	1
STU001	STU001-1005	1005	10	64	YEARS	>= 60 Years	2
STU001	STU001-1006	1006	10	75	YEARS	>= 60 Years	2
STU001	STU001-1007	1007	10	32	YEARS	< 60 Years	1
STU001	STU001-1008	1008	10	83	YEARS	>= 60 Years	2

[27]:
```
colnames(adsl)
```

1. 'STUDYID' 2. 'USUBJID' 3. 'SUBJID' 4. 'SITEID' 5. 'AGE' 6. 'AGEU' 7. 'AGEGR1' 8. 'AGEGR1N' 9. 'SEX' 10. 'RACE' 11. 'RACE1' 12. 'RACE2' 13. 'RACESP' 14. 'SAFFL' 15. 'COMPLFL' 16. 'RANDFL' 17. 'ENRLFL' 18. 'ARM' 19. 'ACTARM' 20. 'TRT01P' 21. 'TRT01PN' 22. 'TRT01A' 23. 'TRT01AN' 24. 'TRTSDT' 25. 'TRTEDT' 26. 'TR01SDT' 27. 'TR01EDT' 28. 'EOSSTT' 29. 'EOSDT' 30. 'DCSREAS' 31. 'EOTSTT' 32. 'DCTREAS' 33. 'RFICDT' 34. 'ENRLDT' 35. 'RANDDT' 36. 'LSTALVDT' 37. 'TRTDURD' 38. 'DTHDT' 39. 'HEIGHTBL' 40. 'WEIGHTBL'

[28]:
```
write_xpt(adsl, "adsl.xpt")
```

[ ]:
```

```