

R Script

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> library(haven)

> #Load CDAI datasets and filter for data at week 6 in patients treated with vedolizumab
> adcdai_171 <- read_sas(„E:/Source Data/NCT01224171/adcdai.sas7bdat“, NULL)
> adcdai_171 <- subset(adcdai_171, VISITNUM==6 & OARM_!=""Placebo")
> adcdai_692 <- read_sas(“E:/Source Data/NCT00783692/adcdai.sas7bdat“, NULL)
> adcdai_692 <- subset(adcdai_692, VISITNUM==6 & OARM_!=""Placebo")

> #Filter data for CDAI
> CDAI_Score_171 <- subset(adcdai_171, CFOBJ=="TOTAL SCORE" & CFCAT=="CDAI",
  select = c("USUBJID", "OARM_", "CFBLCHG", "CFBLPCHG", "CFSTRESN"))
> names(CDAI_Score_171) [names(CDAI_Score_171)=="CFSTRESN"] <- "score"
> names(CDAI_Score_171) [names(CDAI_Score_171)=="CFBLCHG"] <- "diff_score"
> names(CDAI_Score_171) [names(CDAI_Score_171)=="CFBLPCHG"] <- "diff_score_perc"
> CDAI_Score_692 <- subset(adcdai_692, CFOBJ=="TOTAL SCORE" & CFCAT=="CDAI",
  select = c("USUBJID", "OARM_", "CFBLCHG", "CFBLPCHG", "CFSTRESN"))
> names(CDAI_Score_692) [names(CDAI_Score_692)=="CFSTRESN"] <- "score"
> names(CDAI_Score_692) [names(CDAI_Score_692)=="CFBLCHG"] <- "diff_score"
> names(CDAI_Score_692) [names(CDAI_Score_692)=="CFBLPCHG"] <- "diff_score_perc"

> #Combine both datasets
> CDAI_Score <- rbind(CDAI_Score_171, CDAI_Score_692)

> #Check for empty values
> test <- subset(CDAI_Score, is.na(score))

> #Define primary endpoint: clinical remission as CDAI below 150 points
> CDAI_Score$end1 <- 0
> CDAI_Score$end1 [CDAI_Score$diff_score<150] <- 1
> table(CDAI_Score$end1)

> #Load pharmacokinetic dataset and filter for data at week 6 in patients treated with vedolizumab
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> pc_171 <- read_sas("E:/Source Data/NCT01224171/pc.sas7bdat", NULL)
> VedoSerum_171 <- subset(pc_171, VISITNUM==6 & PCTPT=="PREDOSE" & OARM_!="Placebo")
> VedoSerum_171 <- subset(VedoSerum_171, select=c("USUBJID", "PCSTRESN"))
> pc_692 <- read_sas("E:/Source Data/NCT01224171/pc.sas7bdat", NULL)
> VedoSerum_692 <- subset(pc_171, VISITNUM==6 & PCTPT=="PREDOSE" & OARM_!="Placebo")
> VedoSerum_692 <- subset(VedoSerum_692, select=c("USUBJID", "PCSTRESN"))

> #Combine both datasets
> VedoSerum <- rbind(VedoSerum_171, VedoSerum_692)

> #Combine CDAI and serum data and exclude empty values
> data1 <- merge(CDAI_Score, VedoSerum, by="USUBJID")
> data1 <- subset(data1, !is.na(PCSTRESN))
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