

```

*****;
** Program Name : adds.sas                                **;
** Date Created : 07Mar2021                                **;
** Programmer Name : (b) (4), (b)                         **;
** (6)                                                       **;
** Purpose       : Create adds dataset                   **;
** Input data    : ds suppds sv adsl                     **;
** Output data   : adds.sas7bdat                         **;
*****;
%let
oproto=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/bla_euaext_esub_sdtm/saseng/cdisc3_0;
%let prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/euaext_esub_adam/saseng/cdisc3_0;
libname dataprot "&oprot./data" access=readonly;
libname datvprot "&prot./data_val";
*****;

proc printto print="&prot./analysis/esub/output/adds.rpt"
      log="&prot./analysis/esub/logs/adds.log" new;
run;
*****;
* Clean *;
*****;

proc delete data=work._all_;
run;
*****;
* Format *;
*****;

proc format;
  invalue epoch "SCREENING"=1 "OPEN LABEL TREATMENT"=7 "VACCINATION"=26
  "FOLLOW-UP"=31 "REPEAT SCREENING 1"=101 "REPEAT SCREENING 2"=102;
  invalue dsdecod "COMPLETED"=2 "SCREEN FAILURE"=13 "ADVERSE EVENT"=1 "DEATH"=3
  "LOST TO FOLLOW-UP"=5 "OTHER"=7 "PHYSICIAN DECISION"=8 "PREGNANCY"=9
  "PROTOCOL DEVIATION"=11 "STUDY TERMINATED BY SPONSOR"=14
  "WITHDRAWAL BY SUBJECT"=16
  "MEDICATION ERROR WITHOUT ASSOCIATED ADVERSE EVENT"=17
  "NO LONGER MEETS ELIGIBILITY CRITERIA"=18
  "REFUSED FURTHER STUDY PROCEDURES"=25 "WITHDRAWAL BY PARENT/GUARDIAN"=26;
run;
*****;
* Process *;
*****;

/* Readin SDTM and merge DS with SUPPDS */
data ds;
  set dataprot.ds;
  if upcase(dscat)='DISPOSITION EVENT';
run;
*****;
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data suppds;
  set dataprot.suppds;
  where idvar="DSSEQ";
run;

proc sort data=suppds;
  by studyid usubjid idvar idvarval;
run;

proc transpose data=suppds out=suppds_h;
  by studyid usubjid idvar idvarval;
  id qnam;
  idlabel qlabel;
  var qval;
run;

data suppds_h (drop=idvar idvarval _NAME_ _LABEL_);
  set suppds_h;
  DSSEQ=input(idvarval, best12.);
run;

proc sort data=ds out=_ds1;
  by STUDYID USUBJID DSSEQ;
run;

proc sort data=suppds_h out=_ds2;
  by STUDYID USUBJID DSSEQ;
run;

data _spmde1_sdtm_temp_out1;
  merge _ds1(in=d1) _ds2(in=d2);
  by STUDYID USUBJID DSSEQ;
  if d1;
run;

/* Derive ASTDT ASTTM */
data _ds1;
  set _spmde1_sdtm_temp_out1;
  ASTDT=input(DSSTDTC, ??is8601da.);
  format ASTDT date9.;
run;

/* Merge DS with ADSL */
proc sort data=_ds1;
  by USUBJID;
run;

proc sort data=datvprot.adsl out=_ds2;
  by USUBJID;
run;

data _ds3;
  merge _ds1(in=d1) _ds2(in=d2 keep=Usbjid SUBJID SITEID AGE AGEU SEX SEXN RACE

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RACEN ARACE ARACEN RANDFL SAFFL ARM ARMCD ACTARM ACTARMCD TRTSDT TRTSTM
TRTSDTM TRTEDT TRTETM TRTEDTM TRTSEQP TRTSEQA AGEGR1 AGEGR1N COHORT COHORTN
DOSALVL DOSALVNL DOSPLVL DOSPLVNL VAX101DT VAX102DT VAX10UDT VAX201DT
VAX202DT VAX20UDT UNBLNDDT VAX101 VAX102 VAX10U VAX201 VAX202 VAX20U TRT01A
TRT01AN TRT02A TRT02AN TRT01P TRT01PN TRT02P TRT02PN TR01SDT TR01STM TR01SDTM
TR01EDT TR01ETM TR01EDTM TR02SDT TR02STM TR02SDTM TR02EDT TR02ETM TR02EDTM
PHASE PHASEN EOSDCDT EOTDCDT BLDV6DT BLDV7DT AGEGR4 AGEGR4N PEDIMMFL

MULENRFL

PEDREAFL HIVFL DS3KFL EOTXDCDT EOTXDCRS BDCSRDT X1CSRDT STCSRDT AGETR01
AGETRU01 RAND1FL SAF1FL SAF2FL TR01SDT TR01STM TR01SDTM TR01EDT TR01ETM
TR01EDTM TR02SDT TR02STM TR02SDTM TR02EDT TR02ETM TR02EDTM);

by USUBJID;

if d1;

run;

data adds;

length dsdecodn 8 dsphasen 8;
set _ds3;

/* Impute ADT */

if ^missing(DSDTC) then

do;

length yr \$4 mm dd \$2;
yr=substr(DSDTC, 1, 4);
mm=substr(DSDTC, 6, 2);
dd=substr(DSDTC, 9, 2);
;

if yr ne '' then

do;

dflag=' ';

if (dd eq " " or dd eq "-T") and mm ne " " then

do;

dd='01';

;

end;

if mm eq " " or mm eq "--" then

do;

mm='01';

dd='01';

;

end;

newdate=(trim(left(yr))||'-'||trim(left(mm))||'-'||trim(left(dd)));

ADT=input(newdate, ??is8601da.);

format ADT date9.;

end;

drop yr mm dd dflag newdate;

end;

/* Create dsphasen and dsdecodn */

dsphasen=input(dsphase, epoch.);

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dsdecodn=input(dsdecod, ?? dsdecod.);

run;
*****;
* Date Imputation Rules. *;
*****;

/* Create M1PD2DT */
data sv1;
  set dataprot.sv;
  where visit in ("V3_MONTH1_POSTVAX2_L" "V7_MONTH1_S");
  M1PD2DT=input(svstdtc, yymmdd10.);
  format M1PD2DT date9.;
  keep usubjid M1PD2DT;
run;

/* Create M6PD2DT */
data sv2;
  set dataprot.sv;
  where visit in ("V4_MONTH6_L" "V8_MONTH6_S");
  M6PD2DT=input(svstdtc, yymmdd10.);
  format M6PD2DT date9.;
  keep usubjid M6PD2DT;
run;

/* Create M1PX2DT */
data sv3;
  set dataprot.sv;
  where visit in ("V103_MONTH1");
  M1PX2DT=input(svstdtc, yymmdd10.);
  format M1PX2DT date9.;
  keep usubjid M1PX2DT;
run;

/* Correct M1PD2DT */
data sv4;
  set dataprot.sv;
  where visit in ("V7_MONTH1_S_R");
  _M1PD2DT=input(svstdtc, yymmdd10.);
  format _M1PD2DT date9.;
  keep usubjid _M1PD2DT;
run;

proc sql undo_policy=none;
  create table adds as select a.* , b.M1PD2DT, c.M6PD2DT, d.M1PX2DT, e._M1PD2DT
    from adds a left join sv1 b on a.usubjid=b.usubjid left join sv2 c on
      a.usubjid=c.usubjid left join sv3 d on a.usubjid=d.usubjid left join sv4 e on
      a.usubjid=e.usubjid;
quit;

data Adds;
  set adds;
  if cohortn=1.16 then

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M1PD2DT=_M1PD2DT;

if missing(M1PD2DT) and BLDV6DT ne . then
  M1PD2DT=BLDV6DT;

if missing(M6PD2DT) and BLDV7DT ne . then
  M6PD2DT=BLDV7DT;
drop _M1PD2DT;
label M1PD2DT="1 Month Post Dose 2 Visit Date"
  M6PD2DT="6 Months Post Dose 2 Visit Date"
  M1PX2DT="1 Month Post Dose 4 Visit Date";
run;

data adds;
  set adds;
  attrib M1P2CUT label='1 Month PD2 Cutoff Date for Disposition'
    format=date9. M1P2EXC label='Excluded from 1 Month Post Dose 2';
  M1P2CUT=coalesce(BLDV6DT, M1PD2DT);

if M1PD2DT>BLDV6DT. then
  M1P2CUT=M1PD2DT;

if missing(M1P2CUT) then
  do;

    if eosdcdt=eotdcdt. then
      M1P2CUT=eosdcdt;
    else if vax10udt>vax102dt. then
      M1P2CUT=vax10udt+42;
    else if vax102dt ne . then
      M1P2CUT=vax102dt+42;
    else if vax10udt>vax101dt. and vax102dt=. then
      M1P2CUT=vax10udt+42;
    else if vax102dt=. and vax101dt ne . then
      M1P2CUT=vax101dt+42+42;

    if M1P2CUT>=vax201dt. then
      M1P2CUT=vax201dt-1;
  end;

if dsphase="OPEN LABEL TREATMENT" then
  M1P2EXC='Y';
else if dsphase in ("FOLLOW-UP") then
  do;

    if ASTDT>M1P2CUT. then
      M1P2EXC='Y';

    if eosdcdt>eotdcdt and eosdcdt>M1P2CUT. then
      M1P2EXC='Y';
  end;
run;

/* Calculate the study day */

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```

data adds;
set adds;

If ^Missing(AstDt) and ^Missing(TrtSdt) then
do;

  If AstDt lt TrtSdt then
    AstDy=AstDt - TrtSdt;
  Else If AstDt ge TrtSdt then
    AstDy=AstDt - TrtSdt + 1;
end;
;

orig_dsdecod=dsdecod;
run;

data final;
retain STUDYID USUBJID SUBJID SITEID ADT ASTDT ASTDY DSPHASE DSPHASEN DSCAT
DSDECOD DSDECODN DSTERM DSPHASE DSRANGRP M1PD2DT M6PD2DT M1PX2DT M1P2CUT
M1P2EXC USUBJID SUBJID SITEID AGE AGEU SEX SEXN RACE RACEN ARACE ARACEN
RANDFL SAFFL ARM ARMCD ACTARM ACTARMCD TRTS DT TRTSTM TRTS DT TRTED DT TRTETM
TRTED DT TRTSEQP TRTSEQA AGEGR1 AGEGR1N COHORT COHORTN DOSALVL DOSALVNL
DOSPLVL DOSPLVNL VAX101DT VAX102DT VAX10UDT VAX201DT VAX202DT VAX20UDT
UNBLNDDT VAX101 VAX102 VAX10U VAX201 VAX202 VAX20U TRT01A TRT01AN TRT02A
TRT02AN TRT01P TRT01PN TRT02P TRT02PN TR01SDT TR01STM TR01SDTM TR01EDT
TR01ETM TR01EDTM TR02SDT TR02STM TR02SDTM TR02EDT TR02ETM TR02EDTM PHASE
PHASEN EOSDCDT EOTDCDT BLDV6DT BLDV7DT AGEGR4 AGEGR4N PEDIMMFL MULENRFL
PEDREAFL HIVFL DS3KFL EOTXDCDT EOTXDCRS BDCSRDT X1CSRDT STCSRDT AGETR01
AGETRU01 RAND1FL SAF1FL SAF2FL DOMAIN DSSEQ;
set adds(keep=STUDYID USUBJID SUBJID SITEID ADT ASTDT ASTDY DSPHASE DSPHASEN
DSCAT DSDECOD DSDECODN DSTERM DSPHASE DSRANGRP M1PD2DT M6PD2DT M1PX2DT
M1P2CUT M1P2EXC USUBJID SUBJID SITEID AGE AGEU SEX SEXN RACE RACEN ARACE
ARACEN RANDFL SAFFL ARM ARMCD ACTARM ACTARMCD TRTS DT TRTSTM TRTS DT TRTED DT
TRTETM TRTED DT TRTSEQP TRTSEQA AGEGR1 AGEGR1N COHORT COHORTN DOSALVL
DOSALVNL
DOSPLVL DOSPLVNL VAX101DT VAX102DT VAX10UDT VAX201DT VAX202DT VAX20UDT
UNBLNDDT VAX101 VAX102 VAX10U VAX201 VAX202 VAX20U TRT01A TRT01AN TRT02A
TRT02AN TRT01P TRT01PN TRT02P TRT02PN TR01SDT TR01STM TR01SDTM TR01EDT
TR01ETM TR01EDTM TR02SDT TR02STM TR02SDTM TR02EDT TR02ETM TR02EDTM PHASE
PHASEN EOSDCDT EOTDCDT BLDV6DT BLDV7DT AGEGR4 AGEGR4N PEDIMMFL MULENRFL
PEDREAFL HIVFL DS3KFL EOTXDCDT EOTXDCRS BDCSRDT X1CSRDT STCSRDT AGETR01
AGETRU01 RAND1FL SAF1FL SAF2FL DOMAIN DSSEQ);
label ADT='Analysis Date' ASTDT='Analysis Start Date'
ASTDY='Analysis Start Relative Day'
DSDECODN='Standardized Disposition Term (N)'
DSPHASEN='Disposition Phase Code (N)';
run;

proc sort data=final out=datvprot.adds(label='Disposition Analysis Dataset'
DROP=DSRANGRP);
by USUBJID DSSEQ;
quit;

proc printto;
run;

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