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*****;
** Program Name : adds.sas
** Date Created : 17Nov2021
** Programmer Name : (b) (4), (b)
** Purpose : Create adds dataset
** Input data : ds suppds sv adsl
** Output data : adds.sas7bdat
*****;
%let
oprot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/sbla1215_esub_sdtm/saseng/cdisc3_0/data/
sdtm;
%let
protori=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/sbla1215_esub_adam/saseng/cdisc3_0;
%let
prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/sbla1215_esub_adam/saseng/cdisc3_0/analy
sis/eSUB;

libname dataprot "&oprot." access=readonly;
libname datvprot "&protori./data_vai" access=readonly;
libname datvout "&prot./data_vai";

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

proc delete data=work._all_;
run;

*****;
* Format *;
*****;

proc format;
    invalue epoch "SCREENING"=1 "OPEN LABEL TREATMENT"=7 "SUBSTUDY"=24
        "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 */

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```
data ds;
  set dataprot.ds;
  if upcase(dscat)='DISPOSITION EVENT';
run;
```

```
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 qual;
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 _spmdel_sdtm_temp_out1;
  merge _ds1(in=d1) _ds2(in=d2);
  by STUDYID USUBJID DSSEQ;

  if d1;
run;
```

```
/* Derive ASTDT ASTTM */
data _ds1;
  set _spmdel_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
    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
PEDRE AFL
  HIVFL DS3KFL EOTXDCDT EOTXDCRS BDCSRDT X1CSRDT STCSRDT AGETR01 AGETRU01
  EOTDCDT TR01SDT TR01STM TR01SDTM TR01EDT TR01ETM TR01EDTM TR02SDT TR02STM
  TR02SDTM TR02EDT TR02ETM TR02EDTM);
by USUBJID;
if d1;
  if agegr4n=1;
run;

data adds;
length dsdecdn 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.;


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        end;
drop yr mm dd dflag newdate;
end;

/* Create dsphasen and dsdecodn */
dsphasen=input(dsphase, epoch.);
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" "V404_MONTH1_POSTVAX2");
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;

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

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
  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;

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```

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);

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if M1PD2DT>BLDV6DT. then
  M1P2CUT=M1PD2DT;

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if missing(M1P2CUT) then
  do;

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```

    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;

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

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```

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

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```

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

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```

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

```

```

end;
run;

/* Calculate the study day */
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 M1PD2DT M6PD2DT M1PX2DT M1P2CUT M1P2EXC
  USUBJID SUBJID SITEID AGE AGEU SEX SEXN RACE RACEN ARACE ARACEN RANDFL SAFFL
  ARM ARMCD ACTARM ACTARMCD TRTSDT TRTSTM TRTSDETM 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 PEDREAFL HIVFL DS3KFL EOTXDCDT
  EOTXDCRS BDCSRDT X1CSRDT STCSRDT AGETR01 AGETRU01 EOTDCDT DOMAIN DSSEQ;
set adds(keep=STUDYID USUBJID SUBJID SITEID ADT ASTDT ASTDY DSPHASE DSPHASEN
  DSCAT DSDECOD DSDECODN DSTERM DSPHASE M1PD2DT M6PD2DT M1PX2DT M1P2CUT
M1P2EXC
  USUBJID SUBJID SITEID AGE AGEU SEX SEXN RACE RACEN ARACE ARACEN RANDFL SAFFL
  ARM ARMCD ACTARM ACTARMCD TRTSDT TRTSTM TRTSDETM 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 PEDREAFL HIVFL DS3KFL EOTXDCDT
  EOTXDCRS BDCSRDT X1CSRDT STCSRDT AGETR01 AGETRU01 EOTDCDT 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=datvout.adds(label='Disposition Analysis Dataset');
  by USUBJID DSSEQ;
quit;

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proc printto;  
run;
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