

```

*****;
** Program Name : addv.sas                                **;
** Date Created : 17Nov2021                                **;
** Programmer Name : (b) (4), (b)                         **;
** (6)                                                       **;
** Purpose       : Create addv dataset                      **;
** Input data    : dv suppdv adsl                         **;
** Output data   : addv.sas7bdat                          **;
*****;
options mprint mlogic symbolgen mprint symbolgen mlogic nocenter missing=" ";
proc datasets library=WORK kill nolist nodetails;
quit;

**Setup the environment**;
%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";
libname viewpx "/Volumes/app/saseng/prod/cdisc3_0/view/" access=readonly;

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

**** exit if not running a DP algorithm ****;
proc sort data=dataprot.suppdv out=suppdv;
  by usubjid idvarval qnam;
run;

proc transpose data=suppdv out=suppdv1(drop=_NAME__LABEL_);
  by usubjid idvarval;
  var qval;
  id qnam;
  idlabel qlabel;
run;

data suppdv1;
  set suppdv1;
  dvseq=input(idvarval, best.);
run;

proc sort;
  by usubjid dvseq;
run;

```

```

proc sort data=dataprof.dv out=dv;
  by usubjid dvseq;
run;

data _dv1;
  merge dv suppdv1;
  by usubjid dvseq;

proc sort;
  by usubjid;
run;

proc sort data=datvprot.adsl out=adsl;
  by usubjid;
run;

data _dv2;
  merge _dv1(in=a) adsl(in=b);
  by usubjid;
  if a;
  if agegr4n=1;
run;

data _dv3;
  set _dv2;
  format ASTDT date9. aphasdt date9. aphaedt date9. ;
  length aphase $40. aperiodc $20. ;
  label ASTDT='Analysis Start Date' APHASE='Phase' APERIOD='Period'
    APERIODC='Period (C)' PREFL='Pre-treatment Flag' TRPFL='On Treatment Flag';
  p2dt=min(VAX201DT, unblnddt);

  if dvstdtc ne "" then
    astdt=input(dvstdtc, yymmdd10.);

  if brthdt<=astdt<=(trtsdt-1) then
    do;
      aphase='PRE-TREATMENT';
    end;
  else if (.<trtsdt<=astdt and p2dt=.) or (p2dt ne . and .<trtsdt<=astdt<p2dt)
    then
      do;
        aphase='TREATMENT 01';
      end;
  else if .<p2dt<=astdt<trtedt+365 then
    do;
      aphase='TREATMENT 02';
    end;

  if (trtsdt ne . and .<astdt and p2dt=.) or (trtsdt ne . and p2dt
    ne . and .<astdt<p2dt) then
    do;
      aperiod=1;
      aperiodc='Period 01';

```

```

end;
else if .<p2dt<=astdt<=trtsdt+365 then
do;
    aperiod=2;
    aperiodc='Period 02';
end;

if astdt<trtsdt then
prefl='Y';

if substr(aphase, 1, 9)='TREATMENT' then
    TRPFL='Y';
else
    TRPFL='N';
run;

data final;
retain studyid usubjid domain subjid siteid age sex race trtsdt trtedt arm
armcd actarm actarmcd trt01p trt01a trt01pn trt01an agegr1 agegr1n dvseq
dvspid dvterm dvterm1 dvdecod epoch actsite desgtor cape dvcat dvstdtc dvstdy
astdt prefl trpfl randfl phase phasen trtarn trtar trtpn trtp COHORT
COHORTN DOSALVL DOSALVNL DOSPLVL DOSPLVNL DS3KFL AGEGR3N AGEGR3 AGEGR4N
AGEGR4 HIVFL AGETR01 TRTSDTM TRTEDTM TR01SDTM TR01EDTM TR02SDTM TR02EDTM
VAX101 VAX102 VAX10U VAX201 VAX202 VAX20U VAX20UDT UNBLNDDT SAFFL;
set _dv3;
keep studyid usubjid domain subjid siteid age sex race trtsdt trtedt arm armcd
actarm actarmcd trt01p trt01a trt01pn trt01an agegr1 agegr1n dvseq dvspid
dvterm dvterm1 dvdecod epoch actsite desgtor cape dvcat dvstdtc dvstdy astdt
prefl trpfl randfl phase phasen SAFFL COHORT COHORTN DOSALVL DOSALVNL DOSPLVL
DOSPLVNL DS3KFL AGEGR3N AGEGR3 AGEGR4N AGEGR4 HIVFL AGETR01 TRTSDTM TRTEDTM
TR01SDTM TR01EDTM TR02SDTM TR02EDTM VAX101 VAX102 VAX10U VAX201 VAX202 VAX20U
VAX20UDT UNBLNDDT;
run;

proc sort data=final
    out=datvout.addv(label='Protocol Deviations Analysis Dataset');
    by USUBJID ASTDT;
run;

proc printto;
run;

```