

```
/*=====*
```

```
| Covance Study Number   : COV- 106343      |
| Program Name           : d_2addv.sas       |
| Purpose                 : create ADdv      |
| Input Data              : ADAM.ADSL,SDTM.Dv |
| Output Data             : ADAM.ADQSND      |
|                         |                   |
| Macros Called           :                   |
|                         |                   |
| Originally Performed by : Jyothsna Reddy    |
| Date/Time billed        : 24Mar2015        |
|                         |                   |
```

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+=====+
```

```
|                         |
| Modification History    :                   |
|                         |                   |
| Programmer              :                   |
| Date                    :                   |
| Reason for Change       :                   |
```

```
+=====*/
```

```
options notes source source2 nofullstimer validvarname=upcase missing=' ';
```

```
proc datasets lib=work nolist memtype=data kill; quit;
```

```
libname adam "&base2/datasets/adam/cleaned_adam";
```

```
libname sdtm "/cvn/projects/prj/data/000000106343/datasets/sdtm/sdtmx";
```

```
* macro to save output and log to appropriate areas ;
```

```
%m_printto(route=YES);
```

```
*=====;
```

```
* START OF PROGRAM CODE ;
```

```
*=====;
```

```
*****;
```

```
* bring in ADSL ;
```

```
*****;
```

```
data adsl;
```

```
    set adam.adsl;
```

```
run;
```

```
*****;
```

```
* bring in SUPPDV ;
```

```
*****;
```

```
proc transpose data = sdtm.suppdv out=suppdv(drop = _:);
```

```
    var qval;
```

```
    by usubjid idvarval;
```

```
    id qnam;
```

```

        idlabel qlabel;

run;

data suppdv2(drop = idvarval);

        set suppdv;

        dvseq = input(idvarval , best.);

run;

proc sort data=suppdv2;

        by usubjid dvseq;

run;

*****;

* bring in DV ;

*****;

data dv1;

        merge sdtm.dv suppdv2;

        by usubjid dvseq;

        if dvcat ne "MIS-USE OF PRODUCT";

run;

data dv;

        length dvdecod $200 dvcat $60 ;

        set dv1(rename=(dvdecod=dvdecod_ dvcat=dvcat_));

dvdecod=dvdecod_;

dvcat=dvcat_;

```

```
run;

data reason1;

    set adam.adsl;

    where upcase(PPREAS1)^ in ('DISCONTINUED IN PREVIOUS PERIOD' 'NOT IN FAS') and
    cmpcp1fl="N";

    keep usubjid cMPCP: PPREAS;;

run;
```

```
data reason2;

    set adam.adsl;

    where upcase(PPREAS2)^ in ('DISCONTINUED IN PREVIOUS PERIOD' 'NOT IN FAS') and
    cmpcp2fl="N";

    keep usubjid cMPCP: PPREAS;;

run;
```

```
data reason3;

    set adam.adsl;

    where upcase(PPREAS3)^ in ('DISCONTINUED IN PREVIOUS PERIOD' 'NOT IN FAS') and
    cmpcp3fl="N";

    keep usubjid cMPCP: PPREAS;;

run;
```

```
data reason4;

    set adam.adsl;

    where upcase(PPREAS4)^ in ('DISCONTINUED IN PREVIOUS PERIOD' 'NOT IN FAS') and
    cmpcp4fl="N";

    keep usubjid cMPCP: PPREAS;;

run;
```

```

data MID_DV;

    length avalc dvdecod $200 param $100 dvcat $60 ;

set reason1(in=a) reason2(in=b) reason3(in=c) reason4(in=d);

if a then DVCAT="MIS-USE OF PRODUCT IN PERIOD 1";

if b then DVCAT="MIS-USE OF PRODUCT IN PERIOD 2";

    if c then DVCAT="MIS-USE OF PRODUCT IN PERIOD 3";

        if d then DVCAT="MIS-USE OF PRODUCT IN PERIOD 4";

dvdecod="NON-COMPLIANCE TO RANDOMIZATION ARM";

evalcat="NON EVALUABLE";

    dvterm=dvdecod;

    dvsig="MAJOR";

    paramcd = "PROTVIOL";

    avalc=dvterm;

    assess="PRODUCT USE";

    param = "Protocol violation";

    dvrepdtc=" ";RESOL="NA"; SOURCE="PROGRAMMING";

    keep usubjid avalc dvdecod dvcat assess param: dvsig evalcat dvrepdtc RESOL SOURCE;

run;

data dv_all;

set dv(in=a) MID_DV(in=b);

    length avisit $40 atpt avalc $200 param $100 avisitn 8 ;

    format astdt aendt date9. astdtm aendtm datetime13.; * visit details ;

```

avisit = propcase(visit);

avisitn = visitnum;

ATPT=PROPCASE(DVTIMEPT);

if (upcase(dvcat) in ("MIS-RANDOMIZATION" "PRODUCT COMPLIANCE" "VIOLATION" "DURATION OF 24 HOUR COLLECTION" "OTHER") and upcase(dvsig) = 'MINOR') or dvcat = "PROCEDURAL VIOLATION" then
paramcd = "PROCVIOL";

else if upcase(dvcat) in ("MIS-RANDOMIZATION" "PRODUCT COMPLIANCE" "VIOLATION" "DURATION OF 24 HOUR COLLECTION" "OTHER") and upcase(dvsig) = 'MAJOR' then paramcd = "PROTVIOL";

else if upcase(dvcat) = "CONCOMITANT MEDICATION" then paramcd = "CONCMED";

else if upcase(dvcat) = "TIME DEVIATION" then paramcd = "TIMEDEV";

else if upcase(dvcat) = "VISIT WINDOW DEVIATION" then paramcd = "VISWINDV";

else if upcase(dvcat) in ("TIME MISSING") then paramcd = "TIMEMISS";

else if upcase(dvcat) = "ASSESSMENT MISSING" then paramcd = "ASSESISMIS";

else if upcase(dvcat) = "VISIT MISSING" then paramcd = "VISMISS";

If paramcd = "PROCVIOL" then param = "Procedure violation";

else if paramcd = "PROTVIOL" then param = "Protocol violation";

else if paramcd = "CONCMED" then param = "Concomitant medication";

else if paramcd = "TIMEDEV" then param = "Time schedule deviation";

else if paramcd = "VISWINDV" then param = "Visit window deviation";

else if paramcd = "TIMEMISS" then param = "Time missing";

else if paramcd = "ASSESISMIS" then param = "Assessment missing";

else if paramcd = "VISMISS" then param = "Visit missing";

* values;

if a then avalc = dvterm;

```

* dates;

if length(dvstdtc) gt 10 then astdtm = input(dvstdtc,e8601dt.);

if not missing(astdtm) then astdt = datepart(astdtm);

else if length(dvstdtc) = 10 then astdt = input(dvstdtc,ymmdd10.);


if length(dvendtc) gt 10 then aendtm = input(dvendtc,e8601dt.);

if not missing(aendtm) then aendt = datepart(aendtm);

else if length(dvendtc) = 10 then aendt = input(dvendtc,ymmdd10.);


if dvsig=" then dvsig=";

if evalcat=" then evalcat=";


COHORT="";

keep usubjid dvseq avalc dvdecod dvcat assess DVSCAT COHORT DVREPDTC source resol visit:
avisit: dvstdtc astdt:

dvvendtc aendt: atpt: param: epoch dvoth dvsig evalcat;

run;


*****
* Combine ADSL and DV data *;
*****

* find number of periods ;

%m_totper;

proc sort data=dv_all;

by usubjid;

```

```
run;
```

```
data sldv;
```

```
    merge adsl dv_all(in = a);
```

```
    by usubjid;
```

```
    if a;
```

```
    length astday aenday aperiod trtan trtpn 8 trta trtp $40 aperiodc $10;
```

```
    if not missing(astdt) and not missing(trtsdt) then astday = astdt - trtsdt + 1;
```

```
    if not missing(aendt) and not missing(trtsdt) then aenday = aendt - trtsdt + 1;
```

```
    * allocate period and treatment and full and partial dates;
```

```
    %m_perall(dvar1 = asdtm, dvar2 = astdt);
```

```
    if not missing(aperiod) then do;
```

```
        aperiodc = 'Period ' || put (aperiod,1.);
```

```
    end;
```

```
run;
```

```
*****,
```

```
* create output dataset ;
```

```
*****,
```

```
options replace;
```

```
data addv;
```

```
    set sldv;
```

```
    label aperiodc = 'Period (C)';
```



```
run;
```

```
%m_attrib_adam(dset=addv);
```

```
proc sort data = addv out = adam.addv(label= 'Protocol Deviation Analysis Dataset');
```

```
  by usubjid dvstdtc avisitn assess avalc;
```

```
run;
```

```
%m_logchk;
```

```
*=====;
```

```
* END OF PROGRAM CODE                ;
```

```
*=====;
```