

```

/*=====
=====*

| Covance Study Number   : 000000106343          |
|
| Program Name           : d_adae.sas             |
|
| Purpose                : Program to ADAE dataset |
|
| Input Data             : ADAM.ADSL, SDTM.AE, sdtm.SV, sdtm.EX, sdtm.DX, sdtm.SUPPAE,      |
|
| Output Data            : ADAM.ADAE              |
|
| Macros Called          :                       |
|
| Originally Performed by : Paddepal              |
|
| Date                   : 30MAR2015              |
|
|                       |
|=====
=====|

| Modification History          |
|-----|
|
| Modified by                  :                   |
|
| Modification Date           :                   |
|
| Modification Description    :                   |
|
+=====
=====*/

```

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

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

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

```
Data AE;
```

```

set sdtm.AE(rename=(aespid=aespid_));

length aespid $1;

aespid=aespid_;

keep  STUDYID USUBJID AESEQ AESPID AETERM AEDECOD AEBODSYS AEBDSYCD AELLT AELLTCD
AEPTCD

      AEHLT AEHLTCD AEHLGT AEHLGTCD AESOC AESOCCD AESTDTC AEENDTC AESTDY AEENDY AESER

      AESEV AEREL AEACNOTH AEOUT AESCONG AESDISAB AESDTH AESHOSP AESLIFE AECONTRT EPOCH
AEENRTPT ;

run;

data ad;

set adam.adsl;

run;

*****;

* bring in ADSL ;

*****;

data adsl;

      set adam.adsl;

      keep  usubjid subjid: siteid age sex: race height weightbl bmi

      ucpdgr1 ucpdgr1n

      enrfl scrffl exfl  enfl complfl fupfl  SAFBFL SAFAFL fasfl pprot1fl randdt

      pprot2fl pprot3fl pprot4fl randfl lvisdt lvisday  trtsdt trt01p trt01pn

      trt01a trt01an dthfl EXNOTRFL trtsdtm trtstmf

      trtsday trtedtm trtetmf trtedt trteday gpucat1 gpucat1n dtestdt;

run;

proc sort data=adsl;by usubjid;run;

```

```
proc sort data=ae;by usubjid;run;
```

```
data AE_1;  
merge adsl ae(in=a);  
by usubjid;  
if a;  
    ASTDT=input(AESTDTC, IS8601DA.);  
    format ASTDT date9.;  
run;
```

```
Data screen(keep=STUDYID USUBJID SCREENDT);  
    set sdtm.SV(where=(strip(VISIT)="SCREENING"));  
    SCREENDT=input(SVSTDTC, IS8601DA.);  
    format SCREENDT date9.;  
run;
```

```
Proc sql;  
    create table AE_2 as select l.*, r.SCREENDT  
    from AE_1 as l left join screen as r  
    on l.STUDYID=r.STUDYID and l.USUBJID=r.USUBJID;  
quit;
```

```
Data EX;  
    set sdtm.EX(keep=studyid usubjid EXSTDTC);  
    EXSTDTC=input(EXSTDTC, B8601DT16.0);
```

```
proc sort;

by studyid usubjid EXSTDT;

run;
```

```
Data EX_DT;

set EX;

by studyid usubjid EXSTDT;

if first.usubjid then output;

run;
```

```
Data EX_DT;

set EX_DT;

if not missing(exstdt) then do;

EXST=datepart(EXSTDT);

end;

format EXST date9.;

run;
```

```
Data DX;

set sdtm.DX(keep=studyid usubjid DXSTDTC);

if not missing(DXSTDTC) then do;

DXSTDT=input(DXSTDTC, B8601DT16.0);

end;

proc sort;

by studyid usubjid DXSTDT;
```

```
run;
```

```
Data DX_DT;
```

```
set DX;
```

```
by studyid usubjid DXSTDT;
```

```
if first.usubjid then output;
```

```
run;
```

```
Data DX_DT;
```

```
set DX_DT;
```

```
if not missing(DXSTDT) then
```

```
DXST=datepart(DXSTDT);
```

```
format DXST date9.;
```

```
run;
```

```
proc sort data=dx_dt;by usubjid;run;
```

```
proc sort data=ex_dt;by usubjid;run;
```

```
data ae_3;
```

```
merge ae_2(in=a) sdtm.ds(where=(index(dsdecod, "ADVERSE"))) keep = usubjid dsdecod);
```

```
by usubjid;
```

```
if a;
```

```
run;
```

```
/*Check partial AESTDTC*/
```

```
Data partial;
```

```

set AE_3;

if length(strip(AESTDTC))<10 then output;

run;

/* Check if dataset partial has any records*/

/*Derive TRTEMFL*/

Data AE3 (drop=screendt1);

set AE_3;

SCREENDT1=put(SCREENDT,ymmdd10.);

SCYEAR=input(SCAN(SCREENDT1,1,'-'), best.);

SCMON=input(SCAN(SCREENDT1,2,'-'), best.);

aeyear=input(SCAN(AESTDTC,1,'-'), best.);

aemonth= input(SCAN(AESTDTC,2,'-'), best.);

* product emergent same or after first product use;

    if not missing(aestdtc) and not missing (dtestdt) then do;

        if input(AESTDTC, IS8601DA.) ge dtestdt then trtemfl = 'Y';

        else trtemfl = 'N';

    end;

/* Month and year */

else if length(AESTDTC) = 7 then do;

    if aeyear gt scyear or (aeyear = scyear and aemonth ge scomon) then trtemfl = "Y";

    else trtemfl = "N";

```

```

end;

else if aeterm ne "" then trtemfl = "N";

if TRTEMFL="Y" then do;
    if SAFBFL='Y' or SAFAFL='Y' then ANL01FL="Y";
end;

if TRTEMFL="Y" then do;
if SAFBFL='Y' or SAFAFL='Y' then do;
if index(AEACNOTH, 'DISCONTINUED') then ANL02FL="Y";
end;
end;
run;

data suppae01;

set sdtm.suppae;

if idvar ne "AESEQ" then put "WAR" "NING: Unexpected value " qnam= idvar=;

aeseq = input(idvarval, best.);

run;

proc sort data = suppae01;

by usubjid aeseq;

run;

```

```
proc transpose data = suppae01 out = suppae02;
```

```
  by usubjid aeseq;
```

```
  var qval;
```

```
  id qnam;
```

```
  idlabel qlabel;
```

```
run;
```

```
proc sort data=suppae02 ;by usubjid aeseq;run;
```

```
proc sort data=ae3 ;by usubjid aeseq;run;
```

```
Data AE4;
```

```
length aeacnp1 $24 aerelsp $14 aeexpec $14;
```

```
  merge AE3 suppae02(rename=(aeacnp1=aeacnp1_ aeexpec=aeexpec_ aerelsp=aerelsp_ ));
```

```
  by usubjid aeseq;
```

```
  aeacnp1=aeacnp1_;
```

```
  aeexpec=aeexpec_;
```

```
  aerelsp=aerelsp_;
```

```
  if aeacnp1 = "PRODUCT USE INTERRUPTED" then aeacnp1n = 1;
```

```
  else if aeacnp1 = "PRODUCT USE REDUCED" then aeacnp1n = 2;
```

```
  else if aeacnp1 = "PRODUCT USE STOPPED" then aeacnp1n = 3;
```

```
  else if aeacnp1 = "NOT APPLICABLE" then aeacnp1n = 4;
```

```
  else if aeacnp1 = "NONE" then aeacnp1n = 5;
```

```
  if aeout = "DEATH RELATED TO ADVERSE EVENT" then aeoutn = 1;
```

```
  else if aeout = "NOT RECOVERED/NOT RESOLVED" then aeoutn = 2;
```



else if aeout = "RECOVERED/RESOLVED" then aeoutn = 3;

else if aeout = "RECOVERED/RESOLVED WITH SEQUELAE" then aeoutn = 4;

else if aeout = "RECOVERING/RESOLVING" then aeoutn = 5;

else if aeout = "UNKNOWN" then aeoutn = 6;

if length(aestdct) gt 10 then ASTDT = input(scan(aestdct,1,'T'),yymmdd10.);

else if length(aestdct) = 10 then ASTDT = input(aestdct,yymmdd10.);

if length(aeendtc) gt 10 then AENDT = input(scan(aeendtc,1,'T'),yymmdd10.);

else if length(aeendtc) = 10 then AENDT = input(aeendtc,yymmdd10.);

if ASTDT>.z and TRTSDT>.z then ASTDAY = ASTDT - TRTSDT + 1; else ASTDAY = .;

if AENDT>.z and TRTSDT>.z then AENDAY = AENDT - TRTSDT + 1; else AENDAY = .;

if AENDT>.z and ASTDT>.z then AEDURN = AENDT - ASTDT + 1; else AEDURN = .;

if not missing(aedurn) then AEDURU="Days";

/\* Check if any record with AEENRTPT = "ONGOING" and AEENDTC is not missing \*/

if AEENRTPT = "ONGOING" and AEENDTC = " " then AEONGFL = "Y";

else if AETERM ne " " or length(strip(AESTDTC))>0 then AEONGFL = "N";

else AEONGFL = " ";

if AETERM ne " " or length(strip(AESTDTC))>0 or length(strip(AEENDTC))>0 then ANYAEFL = "Y"; else ANYAEFL = "N";

if aerelspn=1 and (.<ASTDT<DTESTDT) or (.<ASTDT<TRTSDTM) then PREFL='Y';

```

if SCRFFL="Y" then PREFL='Y';

else PREFL=' ';

if AESER = "N" then AESERN = 0; else if AESER = "Y" then AESERN = 1;

    if AESEV = "MILD" then AESEVN = 1;

else if AESEV = "MODERATE" then AESEVN = 2;

else if AESEV = "SEVERE" then AESEVN = 3;


if upcase(AEREL) in ("Y" "RELATED") then AERELN = 1;

else if upcase(AEREL) = "NOT RELATED" then AERELN = 0;


if AERELSP = "NOT RELATED" then AERELSPN = 0; else if AERELSP = "RELATED" then AERELSPN = 1;


proc sort;

by USUBJID AESOC AEDECOD DESCENDING AESEVN;

run;

data ae4;

set ae4;

    if TRTEMFL="Y" then do;

if SAFBFL='Y' or SAFAFL='Y' then do;

    if AEACNP1N in (1, 2, 3) then ANL03FL="Y"; else ANL03FL=" ";

    if AECONTRT = 'Y' then ANL04FL="Y"; else ANL04FL=" ";

    if strip(AEACNOTH) ne " " then ANL05FL="Y"; else ANL05FL=" ";

end;

end;

run;

```

```
Data AE5;  
  
  set AE4;  
  
  by USUBJID AESOC AEDECOD DESCENDING AESEVN;  
  
  if trtemfl = 'Y' then do;  
  
    if first.AEDECOD and ANYAEFL="Y" then AOCCPIFL="Y";  
  
  end;  
  
run;
```

```
Proc sort data=AE5;  
  
  by USUBJID AESOC AEDECOD DESCENDING AERELN;  
  
run;
```

```
Data AE6;  
  
  set AE5;  
  
  by USUBJID AESOC AEDECOD DESCENDING AERELN;  
  
  if trtemfl = 'Y' then do;  
  
    if first.AEDECOD and ANYAEFL="Y" then AOCCPRFL="Y";  
  
  end;  
  
  APERIOD = 1;  
  
  APERIODC= "Period 1";  
  
run;
```

```
Data SV_1(keep=STUDYID USUBJID SVSTDTC rename=(SVSTDTC=confinedt));  
  
  set sdtm.SV(where=(visit="DAY 6/DISCHARGE CONFINEMENT"));  
  
run;
```

```
Data SV_2(keep=STUDYID USUBJID SVSTDTC rename=(SVSTDTC=dischargedt));
```

```
set sdtm.SV(where=(visit="DAY 91/DISCHARGE AMBULATORY"));
```

```
run;
```

```
Proc sql;
```

```
create table AE7 as select l.*, r1.confinedt, r2.dischargedt from AE6 as l left join SV_1 as r1 on  
l.STUDYID=r1.STUDYID and l.USUBJID=r1.USUBJID
```

```
left join SV_2 as r2 on l.STUDYID=r2.STUDYID and  
l.USUBJID=r2.USUBJID;
```

```
quit;
```

```
Data AE_7(drop=confinedt dischargedt);
```

```
set AE7;
```

```
condt=input(confinedt,yymmdd10.);
```

```
disdt=input(dischargedt,yymmdd10.);
```

```
format condt disdt date9.;
```

```
if (.< ASTDT <= RANDDT) or missing(randdt) or ENFL='Y' then do; ASPERC = 'Pre-Randomization  
Period';end;
```

```
else if (randdt ne . and RANDDT< ASTDT<= condt) and condt ne . then do; ASPERC = 'Confinement  
Period';end;
```

```
else if (condt < ASTDT <= disdt) and condt ne . and disdt ne . then do; ASPERC = 'Ambulatory  
Period';end;
```

```
else if .z < disdt < ASTDT then ASPERC = 'Safety Follow-up Period';
```

```
if ASPERC = 'Pre-Randomization Period' then ASPER=1;
else if ASPERC = 'Confinement Period' then ASPER=2;
else if ASPERC = 'Ambulatory Period' then ASPER=3;
else if ASPERC = 'Safety Follow-up Period' then ASPER=4;
```

```
if aperiod=1 then do;
    TRTP= TRT01p;
    TRTPN=trt01pn;
    TRTA=trt01a;
    trtan=trt01an;
end;
```

```
run;
```

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

```
* create output dataset ;
```

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

```
data adae;
```

```
set ae_7;
```

```
run;
```

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

```
proc sort data = adae out = adam.adae(label= 'Adverse Event Analysis Dataset');
```

```
  BY USUBJID AETERM AEDECOD AEBODSYS AESTDTC AESPID;
```

```
run;
```

```
%m_logchk;
```