

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

```
| Covance Study Number   : 000000106331          |
```

```
| Program Name           : adcm.sas              |
```

```
| Purpose                : Create Adam Dataset (ADCM) |
```

```
| Input Data             : adsl ,sdtm.cm         |
```

```
| Output Data            : adma.adcm             |
```

```
|                        |
```

```
| Macros Called          :                      |
```

```
| Originally Performed by :paddepalli           |
```

```
| Date                  : 13Mar2015             |
```

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```

```
| Modification History : Original Version      |
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```
| Modified by          :                      |
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| Modification Date    :                      |
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| Modification Reason  :                      |
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```
| Program Version      :                      |
```

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

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

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

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

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

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

```
libname sdtm "/cvn/projects/prj/data/000000106331/datasets/sdtm/sdtmx";
```

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

```
* bring in CM ;
```

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

```
data cm;
```

```
set sdtm.cm;
```

```
keep usubjid cmseq cmspid cmtrt cmdecod cmcat cmindc cmdose cmdosu cmdostot
```

```
    cmroute cmstdtc cmstdy cmendtc cmendy epoch cmenrtpt ;
```

```
run;
```

```
data supp;
```

```
set sdtm.suppcm;
```

```
where qnam in
```

```
('CMPTCD','ATCTXT1','ATCCD1','ATCTXT2','ATCCD2','ATCTXT3','ATCCD3','ATCTXT4','ATCCD4','MHNUM','  
AENUM','OTHER');
```

```
if idvarval>' ' then cmseq=input(idvarval,8.);
```

```
run;
```

```
proc sort data=supp;
```

```
by usubjid cmseq qnam qval;
```

```
run;
```

```
proc transpose data=supp out=supp_t(drop = _:);
```

```
by usubjid cmseq;
```

```

id qnam;

var qval;

idlabel qlabel;

run;


/*Joining CM and SUPPCM */

proc sort data=cm;by usubjid cmseq;run;

proc sort data=supp_t;by usubjid cmseq;run;

data cm_supp;

merge cm supp_t;

by usubjid cmseq;

run;

data cm1;

length aendt astdt 8 CMATCCD1 CMATCCD2 CMATCCD3 CMATCCD4 $8;

set cm_supp;


* dates;

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

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

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

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


format astdt aendt date9.;


CMATC1=ATCTXT1;

```

CMATC2=ATCTXT2;

CMATC3=ATCTXT3;

CMATC4=ATCTXT4;

CMATCCD1=ATCCD1;

CMATCCD2=ATCCD2;

CMATCCD3=ATCCD3;

CMATCCD4=ATCCD4;

IF OTHER="" THEN OTHER="";

keep usubjid aenum MHNUM cmseq cmspid cmtrt cmdecod cmcat cmindc /*cmclas cmclascd*/

cmdose cmdosu cmdostot cmroute cmstdtc astdt cmstdy

cmendtc aendt cmendy cmptcd EPOCH OTHER CMATC1

CMATC2 CMATC3 CMATC4 CMATCCD1 CMATCCD2 CMATCCD3 CMATCCD4

/*CMENRF CMSYCD CMSYN*/ CMENRTPT;

run;

*****,

* bring in ADSL ;

*****,

data adsl;

set adam.adsl;

run;

*****,

```
* bring in SV ;
```

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

```
data sv;
```

```
    set sdtm.sv (where = (visitnum = 1));
```

```
    format scrndt date9.;
```

```
    if length(svstdtc) gt 10 then SCRNDT = input(scan(svstdtc,1,'T'),yymmdd10.);
```

```
    else if length(svstdtc) = 10 then SCRNDT = input(svstdtc,yymmdd10.);
```

```
    keep usubjid scrndt visit;
```

```
run;
```

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

```
* Combine ADSL and data *;
```

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

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

```
data slcm(drop = trt01: cmdecod_ );
```

```
    merge adsl(in=b) sv cm1(in = a rename=(cmdecod=cmdecod_));
```

```
    by usubjid;
```

```
    if a;
```

```
length cmdecod icyear icmon $200;
```

```
CMDECOD=compress(cmdecod_,"KW");
```

```
length aperiod trtan trtpn astday aenday 8 trta trtp $40 aperiodc $10 anycmfl pmfl cmfl $2 ;
```

```
if not missing (astdt) and not missing(trtsdt) then
```

```

        ASTDAY = astdt - trtsdt + 1;

if not missing (aendt) and not missing(trtsdt) then

        AENDDAY = aendt - trtsdt + 1;


        * any meds flag;

        if a then anycmfl = 'Y';

        else if b and not a then do;

                anycmfl = 'N';

        end;


ICCDATE=PUT(ICFDT,YYMMDD10.);

ICYEAR=SCAN(ICCDATE,1,'-');

ICMON=SCAN(ICCDATE,2,'-');


        if anycmfl = 'Y' then do;

                IF LENGTH(CMSTDTC)=10 AND ((astdt lt icfdt) and (aendt lt icfdt)) then pmfl = 'Y';

        /* Year only */

ELSE IF LENGTH(CMSTDTC)=4 AND CMSTDTC<ICYEAR THEN PMFL='Y';

        /* Month and year */

ELSE IF LENGTH(CMSTDTC)=7 AND ((SCAN(CMSTDTC,1,'-')<ICYEAR) OR ((SCAN(CMSTDTC,1,'-')=ICYEAR
AND SCAN(CMSTDTC,2,'-')<ICMON))) THEN PMFL='Y';

                else pmfl = 'N';


        * flag concomitant ;

        if ((astdt ge icfdt) or ((astdt lt icfdt and ((aendt gt icfdt) or missing(cmendtc)))) then cmfl
= 'Y';

```

```
/*Year only*/
```

```
ELSE IF LENGTH(CMENDTC)=4 AND CMENDTC>ICYEAR THEN CMFL='Y';
```

```
/*Month and year*/
```

```
ELSE IF LENGTH(CMENDTC)=7 AND ((SCAN(CMENDTC,1,'-')>ICYEAR) OR  
(SCAN(/*CMSTDTC*/CMENDTC,1,'-')=ICYEAR AND SCAN(CMENDTC,2,'-')/*>*/GE ICMON)) THEN  
CMFL='Y';
```

```
else IF (ASTDT LT ICFDT AND AENDT LT ICFDT) THEN cmfl = 'N';
```

```
IF MISSING(PMFL) THEN DO;
```

```
IF CMFL='Y' THEN PMFL='N';
```

```
ELSE IF CMFL='N' THEN PMFL='Y';
```

```
END;
```

```
IF MISSING(CMFL) THEN DO;
```

```
IF PMFL='Y' THEN CMFL='N';
```

```
ELSE IF PMFL='N' THEN CMFL='Y';
```

```
END;
```

```
IF CMFL='Y' AND PMFL='Y' THEN PUT "WA" "RNING: CMFL and PMFL both = Y. This is  
incorrect, please check." USUBJID=;
```

```
IF CMFL='N' AND PMFL='N' THEN PUT "WA" "RNING: CMFL and PMFL both = N. This is  
incorrect, please check." USUBJID=;
```

```
end;
```

```
IF ANYCMFL='Y' THEN DO;
```

```

    APERIOD=1;

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

END;


if upcase(cmenrtpt)="ONGOING" and missing(CMENDTC) then cmongfl="Y";
else cmongfl="N";


if aenum ne "" then DUEAEFL="Y";
else DUEAEFL="N";

if mhnum ne "" then DUEMHFL="Y";
else DUEMHFL="N";


        if aperiod=1 then do;

            TRTP= TRT01p;

            TRTPN=trt01pn;

            TRTA=trt01a;

            trtan=trt01an;

        end;

run;

* check or excluded medications ;

*****;


proc import

    datafile="/cvn/projects/prj/data/000000106331/source/bannedmeds_14Apr2015.xlsx"

```



```

out=medlist

replace

        dbms=xlsx;

datarow=2;

getnames=NO;

run;

proc sort data = medlist(RENAME=(J=cmtrt_pt Y=cyp1a2_ Z=cyp2a6_ AA=_11_DTX_B2_ AB=HALFLIFE))
out= med (keep=cmtrt_pt cyp1a2_ cyp2a6_ _11_DTX_B2_ HALFLIFE) /*(rename = (a = check))*/ ;

        by cmtrt_pt cyp1a2_ cyp2a6_ _11_DTX_B2_ ;

run;

data med1 (drop= cmtrt_pt cyp1a2_ cyp2a6_ _11_DTX_B2_ ) ;

set med;

length cmdecod $200;

CMDECOD=compress(cmtrt_pt, 'KW');

cyp1a2=compress(cyp1a2_ , 'KW');

cyp2a6=compress(cyp2a6_ , 'KW');

_11_DTX_B2=compress(_11_DTX_B2_ , 'KW');

run;

proc sort data=med1 nodup dupout=dups; by cmdecod HALFLIFE; run;

Proc sql;

create table cma as

```

```
select l.*, r1.cyp1a2, r1.cyp2a6, r1._11_DTX_B2,r1.half-life from slcm as l left join med1 as r1 on  
l.cmdecod=r1.cmdecod
```

```
order by usubjid, cmdecod;
```

```
quit;
```

```
data cma;
```

```
set cma;
```

```
length CRIT1FL CRIT2FL CRIT3FL $2 CRIT1 CRIT2 CRIT3 $200;
```

```
CRIT1 = 'Affects CYP2A6';
```

```
if strip(CYP2A6) ="Y" then CRIT1FL="Y" ;
```

```
else CRIT1FL="N" ;
```

```
CRIT2= 'Affects CYP1A2';
```

```
if strip(CYP1A2) ="Y" then CRIT2FL="Y" ;
```

```
else CRIT2FL="N" ;
```

```
CRIT3='Affects 11-DTX-B2';
```

```
if strip(_11_DTX_B2)="Y" then CRIT3FL="Y" ;
```

```
else CRIT3FL="N" ;
```

```
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 cma1 as select l.*, r1.confinedt, r2.dischargedt from cma 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 cma2(drop=confinedt dischargedt);
```

```
set cma1;
```

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

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

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

```
if trtpn ne 99 then do;
```

```
if (< ASTDT <= RANDDT) or missing(randdt) 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;

end;

run;

*****;

* check tie up with AE ;

*****;


data adcm;

set cma2;

run;


%m_attrib_adam(dset=ADCM);


proc sort data = adcm out = adam.adcm(label= 'Concomitant Medication Analysis Dataset');

    by usubjid cmdecod cmtrt cmstdtc cmcat cmindc;

run;


proc compare base = adam.adcm compare = qadam.qadcm listobs listvar;

run;

```

%m_logchk;