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options notes nosource;
proc datasets lib=work nolist memtype=data kill; quit;
* macro to save output and log to appropriate areas ;
%_mprintto;
%put NOTE:
=====;
%put NOTE: Covance Study Number : 000000106324;
%put NOTE: Client Protocol ID   : ZRHR-REXC-03-EU;
%put NOTE: Program Name        : d_2ADCM.sas;
%put NOTE: Purpose              : create ADCM dataset;
%put NOTE: ;
%put NOTE: Input Data           : STDLIB.ADCM SDTM.CM SDTM.SUPPCM
SDTM.SV;
%put NOTE: Output               : ADAM.ADCM;
%put NOTE: Macros Called        : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by       : cvn_smulholl;
%put NOTE: Creation Date       : 2013-10-18;
%put NOTE: SAS Version         : 9.3;
%put NOTE: ;
%put NOTE: == Latest Run
=====;
%put NOTE: Run by               : &sysuserid;
%put NOTE: Date/Time            :
%sysfunc(putn(%sysfunc(date()),e8601da.))T%sysfunc(putn(%sysfunc(time()),
e86011z.));
%put NOTE: ;
%put NOTE: == Modification History
=====;
%put NOTE: Date      Initials   No. Reason;
%put NOTE: 29Nov2013  SM        1) Remove NONE text as source is
SDTM variable CMTRT;
%put NOTE: 29Apr2014  KB        2) Added EPOCH and OTHER to keep;
%put NOTE: 29Apr2014  KB        3) Removed format from CMSEQ;
%put NOTE: 29Apr2014  KB        4) Amended PMFL and CMFL for partial
dates and added in checks;
%put NOTE: 29Apr2014  KB        5) Amended CRIT1FL and format of CRIT1;
%put NOTE: 29Apr2014  KB        6) Added CMSYCD and CMSYN to keep
statement;
%put NOTE: 29Apr2014  KB        7) Added ATC data;
%put NOTE: 29Apr2014  KB        8) Amended warning for check AE;
%put NOTE: 29Apr2014  KB        9) Added CMENRF to keep;
%put NOTE: 29Apr2014  KB        10) Dropped unused variables;
%put NOTE: 29Apr2014  KB        11) Amended uninitialized in log with
MHNUM;
%put NOTE: 13May2014  KB        12) Amended formats of CMONGFL DUEAEFL
DUEMHFL;
%put NOTE: 13May2014  KB        13) Amended derivation of flags for
partial dates;
%put NOTE: 15May2014  KB        14) Added CRIT2 and CRIT2FL;
%put NOTE: 15May2014  KB        15) Removed format from OTHER;
%put NOTE: 15May2014  KB        16) Study specific hard coding due to
data issue;
%put NOTE: 15May2014  KB        17) Added upcase to check for CRIT2;

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%put NOTE: 04Jun2014    KB           18) Commented out section on checking
against AE;
%put NOTE: 04Jun2014    KB           19) Removed update 11 and added MHNUM
to keep;
%put NOTE: 26Jun2014    JM           20) Use CMENRTPT to replace CMENRF for
ONGONING information due to CMENRF was removed from CM dataset;
%put NOTE: 27Jul2014    KB           21) Added EXNOTRFL;
%put NOTE: 12Sep2014    KB           22) Removed warnings to log regarding
partial dates as no longer needed;
%put NOTE: 12Sep2014    KB           23) Added FASFL & PPROTFL to ADSL keep;
%put NOTE: ;
%put NOTE: ;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

*=====;
* START OF PROGRAM CODE                                     ;
*=====;
*****;
* bring in ADSL ;
*****;

data adsl;
    set adam.adsl;
    keep studyid usubjid subjid: siteid age sex: race height weightb1
bmi ucpdgr1 ucpdgrln nicogr1 nicogrln targr1 targrln cobl
        enrfl scrffl complfl saffl fupfl randfl exfl EXNOTRFL enfl
trt: tr01: trtsdt dthfl icfdt FASFL PPROTFL; /* 21) KB 27Jul2014 */ /*
23) KB 12Sep2014 */
run;

*****;
* bring in SUPPCM ;
*****;

proc transpose data = sdtm.suppcm out=suppcm(drop = _:);
    var qval;
    by usubjid idvarval;
    id qnam;
    idlabel qlabel;
run;

data suppcm2(drop = idvarval);
    set suppcm;
    /* format cmseq 8.;*/ /* 3) KB 29Apr2014 */
    cmseq = input(idvarval,best.);
run;

*****;
* bring in CM      ;

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*****;

data cm;
    merge sdtm.cm suppcm2;
    by usubjid cmseq;
    format astdt aendtc date9. cmongfl dueaefl duemhfl /*$2.*/$8. CMATC1
CMATC2 CMATC3 CMATC4 /*OTHER*/ $200. /* 7) KB 29Apr2014 */ /* 12) KB
13May2014 */ /* 15) KB 15May2014 */
        CMATCCD1 CMATCCD2 CMATCCD3 CMATCCD4 $8. ; /* 7) KB 29Apr2014 */
    * dates;
    if length(cmstdtc) gt 10 then astdt =
input(scan(cmstdtc,1,'T'),ymmdd10.);
    else if length(cmstdtc) = 10 then astdt = input(cmstdtc,ymmdd10.);
    if length(cmendtc) gt 10 then aendtc =
input(scan(cmendtc,1,'T'),ymmdd10.);
    else if length(cmendtc) = 10 then aendtc = input(cmendtc,ymmdd10.);

    /*IF MHNUM='' THEN MHNUM=''; *//* 11) KB 29Apr2014 */ /* 19) KB
04Jun2014 */

    *flags;
    * ongoing;
/*    if cmenrf = 'ONGOING' then cmongfl = 'Y';*/
    if cmenrtpt = 'ONGOING' and missing(CMENDTC) then cmongfl = 'Y'; /*
20) JM 26JUN2014*/
    else cmongfl = 'N';
    * AE;
    if not missing(aenum) then dueaefl = 'Y';
    else dueaefl = 'N';
    * Medical history;
    if not missing(mhnum) then duemhfl = 'Y';
    else duemhfl = 'N';

/* 7) START KB 29Apr2014 */
CMATC1=ATCTXT1;
CMATC2=ATCTXT2;
CMATC3=ATCTXT3;
CMATC4=ATCTXT4;
CMATCCD1=ATCCD1;
CMATCCD2=ATCCD2;
CMATCCD3=ATCCD3;
CMATCCD4=ATCCD4;

    IF OTHER='' THEN OTHER='';
/* 7) END KB 29Apr2014 */

    *some supp variables missing - need to mend when available;
    keep usubjid aenum MHNUM cmseq cmspid cmtrt cmdecod cmcat cmindc
/*cmclas cmclascd*/ cmdose cmdosu cmdostot cmroute cmstdtc /* 19) KB
04Jun2014 */
        astdt cmstdy cmendtc aendtc cmendy cmongfl dueaefl duemhfl
cmptcd EPOCH OTHER CMATC1 CMATC2 CMATC3 CMATC4 CMATCCD1 CMATCCD2 CMATCCD3
CMATCCD4 /* 2) KB 29Apr2014 */ /* 7) KB 29Apr2014 */

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        CMSYCD CMSYN /*CMENRF*/ CMENRTPT; /* 6) KB 29Apr2014 */ /* 9) KB
29Apr2014 */ /* 20) JM 26JUN2014*/
run;

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*****;
* bring in SV ;
*****;

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data sv;
    set sdtm.sv (where = (visit = 'SCREENING'));
    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;
run;

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

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/* macro to allocate period and actual treatment information from ADSL */
%_mtotper;

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data slcm(drop = trt01: tr01: astdtm icfdt);
    merge adsl(in=b) sv cm(in = a);
    by usubjid;
    format aperiod trtan trtpn astday aenday 8. trta trtp $40. aperiodc
$10. anycmfl pmfl cmfl $2. cmatc2 check $200.;
    astday = astdt - trtsdt + 1;
    aenday = aendt - trtsdt + 1;
    astdtm = .; * for macro below to work ;

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/* 4) START KB 29Apr2014 */
ICCHAR=PUT(ICFDT,YMMDD10.);
ICYEAR=SCAN(ICCHAR,1,'-');
ICMON=SCAN(ICCHAR,2,'-');
/* 4) END KB 29Apr2014 */

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    * any meds flag;
    if a then anycmfl = 'Y';
    else if b and not a then do;
        anycmfl = 'N';
        *cmtrt = 'NONE';/* 1) SM 29Nov2013 */
    end;
    if anycmfl = 'Y' then do;
        * flag prior ;
        /* Full date */
        IF LENGTH(CMSTDTC)=10 AND /*if not missing(cmstdtc) and*/
((astdt lt icfdt) and (aendt lt icfdt)) AND CMONGFL='N' then pmfl = 'Y';
/* 4) KB 29Apr2014 */
    /* Year only */

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ELSE IF LENGTH(CMSTDTC)=4 AND CMSTDTC<ICYEAR AND CMONGFL='N' THEN
PMFL='Y'; /* 4) KB 29Apr2014 */
/* Month and year */
ELSE IF LENGTH(CMSTDTC)=7 AND ((SCAN(CMSTDTC,1,'-')<ICYEAR) OR
((SCAN(CMSTDTC,1,'-')=ICYEAR AND SCAN(CMSTDTC,2,'-')<ICMON))) AND
CMONGFL='N' THEN PMFL='Y'; /* 4) KB 29Apr2014 */
/* else if not missing(cmstdtc) and length(cmstdtc) lt 10 then
put 'War' 'ning: Check allocation of flags as partial dates: '
cmstdtc=;*/ /* 22) KB 12Sep2014 */
/*else pmfl = 'N';*/ /* 22) KB 12Sep2014 */
* check;
/*if cmcat = 'PRIOR MEDICATION' AND CMONGFL='N' and pmfl =
'N' then put 'USER WARN' 'ING: check prior medication flag: ' usubjid =
cmstdtc= cmendtc= icfdt=;*/ /* 4) KB 29Apr2014 */ /* 22) KB 12Sep2014 */

* 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'; /* 4)
KB 29Apr2014 */
/*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'; /* 4) KB 29Apr2014 */ /* 13) KB 13May2014 */
/* else if length(cmstdtc) lt 10 then put 'War' 'ning: Check
allocation of flags as partial dates: ' cmstdtc=;*/
else IF (ASTDT LT ICFDT AND AENDT LT ICFDT) THEN cmfl = 'N';
/* 4) KB 29Apr2014 */
/*ELSE IF LENGTH(CMSTDTC) LT 10 THEN PUT 'War' 'ning: Check
allocation of flags as partial dates: ' cmstdtc=;*/ /* 4) KB 29Apr2014 */
/* 22) KB 12Sep2014 */
* check;
/* if cmcat = 'CONCOMITANT MEDICATION' and cmfl = 'N' then put
'USER WARN' 'ING: check concomitant medication flag: ' usubjid = cmstdtc=
cmendtc= icfdt=;*/ /* 22) KB 12Sep2014 */

/* 4) START KB 29Apr2014 */
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;
/* TEMPFIX DUE TO DATA ISSUE MAY NEED TO BE CHANGED LATER - KB 15May2014
*/
IF USUBJID='ZRHR-REXC-03-EU-BIO-0181' AND CMFL='N' AND PMFL='N'
THEN PMFL='Y'; /* 16) KB 15May2014 */
/* TEMPFIX OVER - KB 15May2014 */

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

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        IF CMFL='N' AND PMFL='N' THEN PUT "WA" "RNING: CMFL and PMFL
both = N. This is incorrect, please check." USUBJID=;
/* 4) END KB 29Apr2014 */
    end;

    * declare full and partial dates for deriving period;
/* 13) START KB 13May2014 */
    IF ANYCMFL='Y' THEN DO;
        %_mperall(dvar1 = astdtm, dvar2 = astdt);

        aperiodc = 'Period '||put(aperiod,1.);
    END;
/* 13) END KB 13May2014 */

    check = lowercase(/*cmatc2*/CMDECOD); /* 5) KB 29Apr2014 */
    DUMMY=1; /* 5) KB 29Apr2014 */

run;

*****;
* check or excluded medications ;
*****;

proc import

datafile="/cvn/projects/prj/data/000000106324/source/bannedmeds.xlsx"
    out=work.medlist
    replace
    dbms=xlsx;
    range="a1:a68";
    getnames=no;
run;

proc sort data = medlist(rename = (a = check)) NODUPKEY; /* 5) KB
29Apr2014 */
    by check;
run;

/* 5) START KB 29Apr2014 */
DATA MEDLIST2A;
    SET MEDLIST;
    DUMMY=1;
RUN;

PROC TRANSPOSE DATA=MEDLIST2A OUT=MEDLIST2;
    BY DUMMY;
    VAR CHECK;
RUN;
/* 5) END KB 29Apr2014 */

proc sort data = slcm;
    by check;
run;

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data cm2/*(drop = check)*/; /* 5) KB 29Apr2014 */
    merge slcm(in = cm) /*medlist*/MEDLIST2(in = list); /* 5) KB
29Apr2014 */
    by DUMMY/*check*/; /* 5) KB 29Apr2014 */
    if cm;
    format crit1fl $2. crit1 /*$50.*/$200.; /* 5) KB 29Apr2014 */
    crit1 = 'Affects CYP2A6';
/*    if cm and list then crit1fl = 'Y';*/ /* 5) KB 29Apr2014 */

/* 5) START KB 29Apr2014 */
    ARRAY A [66] COL1 - COL66;
    DO I=1 TO 66;
        IF INDEX(COMPRESS(CHECK,, 'KA'), COMPRESS(A[I],, 'KA')) THEN DO;
            CHECK2=COMPRESS(A[I],, 'KA');
            IF CMENDY GE -16 OR /*CMENRF*/ CMENRTPT='ONGOING' THEN DO; /*
20) JM 26JUN2014*/
                CRIT1FL = 'Y';
            END;
        END;
    END;

    IF CRIT1FL NE 'Y' AND ANYCMFL='Y' THEN CRIT1FL='N';

    IF CRIT1FL EQ '' THEN CRIT1='';
/* 5) END KB 29Apr2014 */

/*    else crit1fl = 'N';*/ /* 5) KB 29Apr2014 */
run;

*****;
* check tie up with AE ;
*****;

/* 18) START KB 04Jun2014 */
/*data chkcm(keep = subjidn chkae cmtrt cmindc cmstdtc cmendtc);*/
/*    set cm2(where = (not missing(aenum)));*/
/*    chkae = input(aenum,best.);*/
/*run;*/
**/
/*proc sort data = chkcm;*/
/*    by subjidn chkae;*/
/*run;*/

/*data chkae(keep = subjidn aeterm aestdtc aeendtc chkae TRTEMFL);*/ /*
8) KB 29Apr2014 */
/*    set adam.adae(where = (anl04fl = 'Y'));*/
/*    chkae=input(aespid,best.);*/
/*run;*/
**/
/*proc sort data = chkae;*/
/*    by subjidn chkae;*/
/*run;*/

/*data chkcmae(DROP=TRTEMFL);*/ /* 8) KB 29Apr2014 */

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/*      merge chkae(in = a) chkcm(in = b);*/
/*      by subjdn chkae;*/
/*      if a and not b then put 'USER WARN' 'ING: AE states meds taken but
none in CM: ' subjdn =  chkae= aeterm = aestdtc = aeendtc =; */
/*      if b and not a AND TRTEMFL='Y' then put 'USER WARN' 'ING: CM states
meds taken for AE but none in AE: ' subjdn =  chkae= cmtrt = cmstdtc =
cmendtc =; *//* 8) KB 29Apr2014 */
/*run;*/
/* 18) END KB 04Jun2014 */

/* 10) START KB 29Apr2014 */
/*DATA CM3;*/
/*      SET CM2;*/
/**/
/*      DROP CMENRF DUMMY CHECK COL1-COL66 ICCHAR ICMON ICYEAR _NAME_
_LABEL_ I CHECK2;*/
/*RUN;*/
/* 10) END KB 29Apr2014 */

/* 14) START KB 15May2014 */
PROC IMPORT

DATAFILE="/cvn/projects/prj/data/000000106324/source/bannedmeds.xlsx"
      OUT=WORK.MEDLIST1A2
      REPLACE
      DBMS=XLSX;
      RANGE="A1:A68";
      SHEET="CYP1A2";
      GETNAMES=NO;
RUN;

PROC SORT DATA = MEDLIST1A2 (WHERE=(INDEX(CHECK,'CYP ')=0) RENAME = (A =
CHECK)) NODUPKEY ;
      BY CHECK;
RUN;

DATA MEDLIST1A2B;
      SET MEDLIST1A2;
      DUMMY=1;
RUN;

PROC TRANSPOSE DATA=MEDLIST1A2B OUT=MEDLIST1A2C (RENAME=(COL1 - COL59 =
REL1 - REL59));
      BY DUMMY;
      VAR CHECK;
RUN;

PROC SORT DATA = CM2;
      BY CHECK;
RUN;

DATA CM1A2;
      MERGE CM2 (IN = CM) MEDLIST1A2C (IN = LIST);
      BY DUMMY;

```



```

        IF CM;
        FORMAT CRIT2FL $2. CRIT2 $200.;
        CRIT2 = 'Affects CYP1A2';

        ARRAY B [59] REL1 - REL59;
        DO I=1 TO 59;
            IF
INDEX(UPCASE(COMPRESS(CHECK,, 'KA')),UPCASE(COMPRESS(B[I],, 'KA'))) THEN
DO; /* 17) KB 15May2014 */
            CHECK4=COMPRESS(B[I],, 'KA');
            IF CMENDY GE -16 OR /*CMENRF*/ CMENRTPT='ONGOING' THEN DO; /*
20) JM 26JUN2014*/
                CRIT2FL = 'Y';
            END;
        END;
    END;

    IF CRIT2FL NE 'Y' AND ANYCMFL='Y' THEN CRIT2FL='N';

    IF CRIT2FL EQ '' THEN CRIT2='';
RUN;

DATA CM1A2A;
    SET CM1A2;

    DROP /*CMENRF*/ CMENRTPT DUMMY CHECK COL1-COL66 ICCHAR ICMON ICYEAR
    _NAME_ _LABEL_ I CHECK2 REL1-REL59 CHECK4; /* 20) JM 26JUN2014*/
RUN;
/* 14) END KB 15May2014 */
*****;
* create output dataset ;
*****;

options replace;

data adcm;
    set stdlib.adcm /*cm2*//*CM3*/CM1A2A; /* 10) KB 29Apr2014 */ /*
14) KB 15May2014 */
        label aperiodc = 'Period (C)';
run;

proc sort data = adcm out = adam.adcm(label= 'Concomitant Medication
Analysis Dataset');
    by usubjid cmdecod cmtrt cmstdtc cmcat cmindc;
run;

options noreplace;
proc printto; run;
*=====;
* END OF PROGRAM CODE ;
*=====;

```