

```

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_2ADPE.sas;
%put NOTE: Purpose : create ADPE dataset;
%put NOTE: ;
%put NOTE: Input Data : STDLIB.ADPE SDTM.PE SDTM.SUPPPE;
%put NOTE: Output : ADAM.ADPE;
%put NOTE: Macros Called : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by : cvn_smulholl;
%put NOTE: Creation Date : 2013-09-23;
%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: 02Dec2013 SM 1) Remove VISITx variables;
%put NOTE: 03Dec2013 SM 2) Add PARAMN and code;
%put NOTE: 3) Amend DESC code;
%put NOTE: 30Apr2014 KB 4) Removed PESEQ format;
%put NOTE: 30Apr2014 KB 5) Added EPOCH to keep statement;
%put NOTE: 30Apr2014 KB 6) Amended PARAM and PARAMCD for Chest
XRay;
%put NOTE: 30Apr2014 KB 7) Added BASE ABLFL and SHIFT1;
%put NOTE: 30Apr2014 KB 8) Added ANL01FL;
%put NOTE: 14May2014 KB 9) Added format to PARAMN;
%put NOTE: 14May2014 KB 10) Amended sorting by key variables;
%put NOTE: 14May2014 KB 11) Amended DESC;
%put NOTE: 27May2014 KB 12) Removed format from PECLSIG;
%put NOTE: 27Jul2014 KB 13) Added EXNOTRFL;
%put NOTE: 13Sep2014 KB 14) Amended ABLFL;
%put NOTE: 13Sep2014 KB 15) Added clinical significance to
SHIFT1;
%put NOTE: 13Sep2014 KB 16) Added FASFL & PPROTFL to keep;
%put NOTE: 13Sep2014 KB 17) Added PEALL to PARAMNs;
%put NOTE: 15Sep2014 KB 18) Amended PARAMs for different types
of OTHER;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';

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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 ucpdgr: nicogr: targr: cobl
        enrfl scrffl complfl fupfl saffl randfl trt: tr01: dthfl
exfl EXNOTRFL enfl FASFL PPROTFL; /* 13) KB 27Jul2014 */ /* 16) KB
13Sep2014 */
run;

proc sort data = adsl;
    by usubjid;
run;

*****;
* pick up SUPPPE ;
*****;

proc transpose data = sdtm.supppe out = supppe(drop = _:) prefix=v;
    var qval;
    by usubjid idvarval;
    id qnam;
run;

data supppe2(drop = vpeclsig);
    set supppe;
    format/* pseq 8.*/ /*peclsig $2.*/; /* 4) KB 30Apr2014 */ /* 12)
KB 27May2014 */
    pseq = input(idvarval,best.);
    peclsig = left(trim(vpeclsig));
run;

proc sort data = supppe2;
    by usubjid pseq;
run;

*****;
* bring in PE ;
*****;

proc sort data = sdtm.pe out = pe;
    by usubjid pseq;
run;

data pe2;
    merge pe supppe2;

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        by usubjid pseq;
        format avisitn PARAMN 8. paramcd $8. param avisit $40. /* 9) KB
14May2014 */
                adt date9. avalc desc $200. /*ABLFL $2.*;/ /* 7) KB
30Apr2014 */ /* 14) KB 13Sep2014 */
/* 6) START KB 30Apr2014 */
/*      paramcd = petestcd;*/
/*      param = trim(petest);*/
IF PECAT NE 'CHEST X-RAY' THEN DO;
    PARAMCD = PETESTCD;
    PARAM = TRIM(PETEST);
END;
ELSE DO;
    PARAMCD='CHESTX';
    PARAM='Chest X-ray';
END;
/* 6) END KB 30Apr2014 */
    if pestat = 'NOT DONE' then avalc = 'Not Examined';
    else if pestresc = 'NORMAL' then avalc = propcase(pestresc);
    else if index(pestresc,'ABNORMAL') then do;
        DESCLEN = INDEX(PESTRESC,'-'); /* 3) SM 03Dec2013 */
        avalc = trim(propcase(scan(pestresc,1,'-')));
        /*desc =
propcase(strip(/**/*scan*//*SUBSTR(pestresc,DESCLEN+1*//*2,'-
'/**/*)),'.');*/ /* 3) SM 03Dec2013 */
        DESC=LEFT(TRIM(PROPCASE(TRANWRD(PESTRESC,'ABNORMAL - ','')))); /*
11) KB 14May2014 */
        end;

/* 18) START KB 15Sep2014 */
IF PARAMCD='OTHER' AND NOT MISSING(DESC) THEN DO;
    IF INDEX(SCAN(DESC,1,'-'),'Extremities') THEN DO;
        PARAMCD='OTHEXTRM';
        PARAM='Other - Extremities';
    END;
    ELSE IF INDEX(SCAN(DESC,1,'-'),'Lymph Nodes') THEN DO;
        PARAMCD='OTHLYMN';
        PARAM='Other - Lymph Nodes';
    END;
    ELSE IF INDEX(SCAN(DESC,1,'-'),'Lymphatic System') THEN DO;
        PARAMCD='OTHLYMS';
        PARAM='Other - Lymphatic System';
    END;
    ELSE IF INDEX(SCAN(DESC,1,'-'),'Vascular') THEN DO;
        PARAMCD='OTHVASC';
        PARAM='Other - Vascular';
    END;
END;
/* 18) END KB 15Sep2014 */
/* 2) SM 03Dec2013 */
IF PARAMCD = 'GAPPEAR' THEN PARAMN = 1;
ELSE IF PARAMCD = 'HEENT' THEN PARAMN = 2;
ELSE IF PARAMCD = 'THYROID' THEN PARAMN = 3;

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        ELSE IF PARAMCD = 'HEART' THEN PARAMN = 4;
        ELSE IF PARAMCD = 'CHEST' THEN PARAMN = 5;
        ELSE IF PARAMCD = 'LUNGS' THEN PARAMN = 6;
        ELSE IF PARAMCD = 'GASTRO' THEN PARAMN = 7;
        ELSE IF PARAMCD = 'CVS' THEN PARAMN = 8;
        ELSE IF PARAMCD = 'NEURO' THEN PARAMN = 9;
        ELSE IF PARAMCD = 'SKIN' THEN PARAMN = 10;
        ELSE IF PARAMCD = 'BACK' THEN PARAMN = 11;
        ELSE IF PARAMCD = 'MUSCULO' THEN PARAMN = 12;
        ELSE IF PARAMCD = 'ABDOMEN' THEN PARAMN = 13;
        ELSE IF PARAMCD = 'DENTN' THEN PARAMN = 14;
        ELSE IF PARAMCD = 'OTHER' THEN PARAMN = 15;
/* 18) START KB 15Sep2014 */
        ELSE IF PARAMCD='OTHEXTRM' THEN PARAMN=16;
        ELSE IF PARAMCD='OTHLYMN' THEN PARAMN=17;
        ELSE IF PARAMCD='OTHLYMS' THEN PARAMN=18;
        ELSE IF PARAMCD='OTHVASC' THEN PARAMN=19;
/* 18) END KB 15Sep2014 */
        ELSE IF PARAMCD='CHESTX' THEN PARAMN=20; /* 6) KB 30Apr2014 */
        ELSE IF PARAMCD='PEALL' THEN PARAMN=99; /* 17) KB 13Sep2014 */
        ELSE PUT 'USER WARN' 'ING: PARAMN not allocated: ' USUBJID =
PARAMCD = ;

        avisitn = visitnum;
        avisit = propcase(visit);
        if not missing(pedtc) then adt = input(pedtc,yymmdd10.);
        adtm = .; * set up for period macro;

        /*IF AVISIT='Day -2' AND PESTAT NE 'NOT DONE' THEN ABLFL='Y'; *//*
7) KB 30Apr2014 */ /* 14) KB 13Sep2014 */

        keep usubjid peseq pespid pecat param: avalc pereasnd pestat
visitnum visit avisit:
        adt adtm pedtc pedy peclsig desc PARAMN EPOCH /*ABLFL*/; /*
2) SM 03Dec2013 */ /* 5) KB 30Apr2014 */ /* 7) KB 30Apr2014 */ /* 14)
KB 13Sep2014 */
run;

* pick up all versions of parmcd=other;
proc sort data=pe2;
    by parmcd param;
run;

data pe2a;
    set pe2;
    by parmcd param;
run;

proc sort data = pe2a;
    by usubjid;
run;

/* Obtain Baselines*/
/* 14) START KB 13Sep2014 */

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DATA SV;
  SET SDTM.SV(WHERE=(VISIT=('DAY 1')));
  FORMAT DAY DATE9.;

  DAY=INPUT(SCAN(SVSTDTC,1,'T'),YYMMDD10.);
  KEEP USUBJID DAY;
RUN;

DATA ABLFL;
  SET PE2A(WHERE=(AVISIT IN ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day
1') AND PESTAT NE 'NOT DONE'));

  KEEP USUBJID PARAMCD AVISIT ADT;
RUN;

PROC SORT DATA=ABLFL;
  BY USUBJID;
RUN;

DATA ABLFL2;
  MERGE ABLFL(IN=A) SV;
  BY USUBJID;
  IF A;
RUN;

DATA ADSLTM;
  SET ADAM.ADSL;
  WHERE TRT01A IN ('CC' 'THS 2.2' 'SA');

  KEEP USUBJID TRTSDTM TRT01A;
RUN;

DATA ABLFL2A;
  MERGE ABLFL2(IN=A) ADSLTM;
  BY USUBJID;
  IF A;
RUN;

PROC SORT DATA=ABLFL2A;
  BY USUBJID PARAMCD ADT;
RUN;

DATA ABLFL3;
  SET ABLFL2A;

  IF TRT01A='SA' THEN DO;
    IF DAY NE . THEN DO;
      IF ADT<DAY AND INDEX(UPCASE(AVISIT),'UNSCHED')=0 THEN
ABLFL2='Y';
      END;
    ELSE IF DAY EQ . THEN DO;
      IF INDEX(UPCASE(AVISIT),'UNSCHED')=0 THEN ABLFL2='Y';
      END;
    END;
  END;

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        ELSE IF TRT01A IN ('CC' 'THS 2.2') THEN DO;
            IF ADT<DATEPART(TRTSDTM) AND INDEX(UPCASE(AVISIT),'UNSCHED')=0
THEN ABLFL2='Y';
        END;
        ELSE IF MISSING(TRT01A) THEN DO;
            IF INDEX(UPCASE(AVISIT),'UNSCHED')=0 THEN ABLFL2='Y';
        END;
    RUN;

PROC SORT DATA=ABLFL3(WHERE=(ABLFL2='Y')) OUT=ABLFL4;
    BY USUBJID PARAMCD ADT;
RUN;

DATA ABLFL5(WHERE=(ABLFL='Y'));
    SET ABLFL4;
    BY USUBJID PARAMCD ADT;
    FORMAT ABLFL $2.;

    IF LAST.PARAMCD THEN ABLFL='Y';

    KEEP USUBJID PARAMCD AVISIT ABLFL;
RUN;

PROC SORT DATA=ABLFL5;
    BY USUBJID PARAMCD AVISIT;
RUN;

PROC SORT DATA=PE2A;
    BY USUBJID PARAMCD AVISIT;
RUN;

DATA PE2BA;
    MERGE PE2A ABLFL5;
    BY USUBJID PARAMCD AVISIT;
RUN;
/* 14) END KB 13Sep2014 */

/* 7) START KB 30Apr2014 */
DATA BASE;
    SET /*PE2A*/PE2BA(WHERE=(ABLFL='Y')); /* 14) KB 13Sep2014 */
    FORMAT BASEC $200.;

    BASEC=AVALC;
    BPECLSIG=PECLSIG; /* 15) KB 13Sep2014 */

    KEEP USUBJID BASEC PARAMCD BPECLSIG; /* 15) KB 13Sep2014 */
RUN;

PROC SORT DATA=BASE;
    BY USUBJID PARAMCD;
RUN;

DATA PE2B;
    MERGE /*PE2A*/PE2BA BASE; /* 14) KB 13Sep2014 */

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        BY USUBJID PARAMCD;
RUN;

DATA PE2C(DROP=BPECLSIG); /* 15) KB 13Sep2014 */
    SET PE2B;
    FORMAT SHIFT1 $50.;

    IF NOT MISSING(AVALC) AND NOT MISSING(BASEC) AND MISSING(ABLFL) AND
    AVISIT NE 'Screening' THEN DO;
    /* 15) START KB 13Sep2014 */
    /*      SHIFT1=STRIP(BASEC) || ' to ' || STRIP(AVALC);*/
        IF NOT MISSING(BPECLSIG) AND NOT MISSING(PECLSIG) THEN SHIFT1 =
    STRIP(BASEC) || ', ' || STRIP(BPECLSIG) || ' to ' ||STRIP(AVALC) || ', '
    || STRIP(PECLSIG);
        ELSE IF NOT MISSING(BPECLSIG) AND MISSING(PECLSIG) THEN
    SHIFT1=STRIP(BASEC) || ', ' || STRIP(BPECLSIG) || ' to ' ||STRIP(AVALC);
        ELSE IF MISSING(BPECLSIG) AND NOT MISSING(PECLSIG) THEN
    SHIFT1=STRIP(BASEC) || ' to ' ||STRIP(AVALC) || ', ' || STRIP(PECLSIG);
        ELSE IF MISSING(BPECLSIG) AND MISSING(PECLSIG) THEN
    SHIFT1=STRIP(BASEC) || ' to ' ||STRIP(AVALC);
    /* 15) END KB 13Sep2014 */
    END;
RUN;
    /* 7) END KB 30Apr2014 */

*****;
* Combine ADSL and PE data *;
*****;
* find periods;
*_mtotper;

data slpe(drop = trt01: tr01: adtm VISIT:); /* 1) SM 02Dec2013 */
    merge adsl /*pe2a*/PE2C(in = a); /* 7) KB 30Apr2014 */
    by usubjid;
    if a;          * only include subject level data is eligibilty issues ;
    format aperiod trtan trtpn aday 8. trta trtp $40. aperiodc $10.;
    aday = adt - trtsdt + 1;
    *_mperall(dvar1 = adtm, dvar2 = adt);
    aperiodc = 'Period ' ||put(aperiod,1.);
run;

    /* 8) START KB 30Apr2014 */
PROC SORT DATA=SLPE;
    BY USUBJID PARAMN AVISITN;
RUN;

DATA SLPE2;
    SET SLPE;
    BY USUBJID PARAMN AVISITN;
    FORMAT ANL01FL $2.;

    * determine if any unscheduled;
    IF INDEX(UPCASE(AVISIT),'UNSCHEDULED') THEN ANL01FL = ' ';
    ELSE IF LAST.AVISITN AND FIRST.AVISITN = 0 THEN ANL01FL = ' ';

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        ELSE ANL01FL = 'Y';
        IF ANL01FL = ' ' THEN PUT "WARN" "ING: Check reason for exclusion
from analysis: " USUBJID = PARAM = AVISIT = ;
        IF PARAMCD/*=*/ IN ('CHESTX' 'PEALL') THEN ANL01FL=' '; /* 17) KB
13Sep2014 */
RUN;
/* 8) END KB 30Apr2014 */

*****;
* create output dataset ;
*****;

options replace;

data adpe;
    set stdlib.adpe /*slpe*/SLPE2; /* 8) KB 30Apr2014 */
label aperiodc = 'Period (C)';
run;

proc sort data = adpe out = adam.adpe(label = 'Physical Examination
Analysis Dataset');
/*    by usubjid avisitn paramcd;*/
    BY USUBJID AVISITN PARAMCD PESPID; /* 10) KB 14May2014 */
run;

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

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