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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_2ADXP.sas;
%put NOTE: Purpose : create ADVS dataset;
%put NOTE: ;
%put NOTE: Input Data : STDLIB.ADXP SDTM.XP SDTM.SUPPXP;
%put NOTE: Output : ADAM.ADXP;
%put NOTE: Macros Called : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by : cvn_smulholl;
%put NOTE: Creation Date : 2013-09-26;
%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: 03Dec2013 SM 1) Amend case of initials and
creation of DESC;
%put NOTE: 30Apr2014 KB 2) Added EPOCH to keep statement;
%put NOTE: 30Apr2014 KB 3) Removed format from XPSEQ;
%put NOTE: 30Apr2014 KB 4) Removed XPCLSIG coding;
%put NOTE: 30Apr2014 KB 5) Amended derivation of PARCAT1;
%put NOTE: 30Apr2014 KB 6) Amended ANL01FL;
%put NOTE: 30Apr2014 KB 7) Amended derived FEVFVC;
%put NOTE: 30Apr2014 KB 8) Amended derivation of PARAM and
PARAMCD;
%put NOTE: 30Apr2014 KB 9) Added XPALL;
%put NOTE: 30Apr2014 KB 10) Added PARAMNs of DOSE and BRONCHO;
%put NOTE: 30Apr2014 KB 11) Amended ABLFL;
%put NOTE: 14May2014 KB 12) Amended sorting by key variables;
%put NOTE: 14May2014 KB 13) Removed format of XPCLSIG;
%put NOTE: 14May2014 KB 14) Amended baselines;
%put NOTE: 15May2014 KB 12) Added ATPT and ATPTN;
%put NOTE: 15May2014 KB 13) Rounded CHG;
%put NOTE: 15May2014 KB 14) Propcased ATPT;
%put NOTE: 15May2014 KB 15) Set SDTM variables to null for
derived FEVFVC;
%put NOTE: 15May2014 KB 16) Amended DESC;
%put NOTE: 15May2014 KB 17) Amended ANL01FL for unscheduleds;
%put NOTE: 15May2014 KB 18) Amended SHIFT1 to only populate for
AVALC present;

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%put NOTE: 15May2014    KB           19) Amended DEVFVC to populate for
unscheduleds;
%put NOTE: 15May2014    KB           20) Amended BVIS to use ATPTN;
%put NOTE: 27Jul2014    KB           21) Added EXNOTRFL;
%put NOTE: 14Sep2014    KB           22) Amended ABLFL;
%put NOTE: 14Sep2014    KB           23) Added clinical significance to
SHIFT1;
%put NOTE: 14Sep2014    KB           24) Added FASFL & PPROTFL to ADSL keep;
%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 ucpdgr: nicogr: targr: cob1
        enrfl scrffl complfl saffl randfl trt: tr01: dthfl enfl
EXNOTRFL exfl fupfl FASFL PPROTFL; /* 21) KB 27Jul2014 */ /* 24) KB
14Sep2014 */
run;

proc sort data = adsl;
    by usubjid;
run;

*****;
* pick up SUPPXP ;
*****;

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

data suppXP2(drop = vxpcLSig);
    set suppXP;
    format /*xpseq 8.*/ /*xpclsig $2.*/; /* 3) KB 30Apr2014 */ /* 13)
KB 14May2014 */
    xpseq = input(idvarval,best.);
    XPCLSIG=STRIP(VXPCLSIG); /* 4) KB 30Apr2014 */
/*    if vxpcLSig = 'NCS' then xpclsig = 'N';*/ /* 4) KB 30Apr2014 */
/*    else if vxpcLSig = 'CS' then xpclsig = 'Y';*/ /* 4) KB 30Apr2014 */

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run;

proc sort data = suppxp2;
    by usubjid xpseq;
run;

*****;
* calculate FEV1/FVC ;
*****;

proc sort data = sdtm.xp out = xp;
    by usubjid xpcat visitnum;
run;

/* 7) START KB 30Apr2014 */
/*data ratio(drop = fev1 fvc);*/
/* merge xp(where = (xptestcd = 'FEV1MEAS') rename = (xpstresn = fev1));*/
/* xp(where = (xptestcd = 'FVCMEAS') rename = (xpstresn = fvc)
keep = usubjid xpcat visitnum xptestcd xpstresn);*/
/* by usubjid xpcat visitnum;*/
/* xptestcd = 'FEV1FVC';*/
/* xptest = 'Check calculated ratio between FEV1/FVC';*/
/* xpstresn = round((fev1 / fvc),0.01);*/
/* xpstresc = left(trim(put(xpstresn,5.2))));*/
/* xporres = trim(xpstresc);*/
/* xporresu = ' ';*/
/* xpstresu = ' ';*/
/* xpseq=.;*/
/*run; */

/* 7) START KB 30Apr2014 */
PROC SORT DATA=XP(WHERE=(XPTSTCD='FEV1FVC' AND NOT MISSING (XPSTRESN)
AND XPSTAT NE 'NOT DONE')) OUT=XPA NODUPKEY;
    BY USUBJID XPSCAT VISITNUM XPTPT; /* 19) KB 15May2014 */
RUN;

DATA XP1A;
    SET XPA;

    PRESENT=1;

    KEEP USUBJID XPSCAT PRESENT VISITNUM XPTPT; /* 19) KB 15May2014 */
RUN;

PROC SORT DATA=XP;
    BY USUBJID XPSCAT VISITNUM XPTPT; /* 19) KB 15May2014 */
RUN;

DATA XPPRESENT;
    MERGE XP XP1A;
    BY USUBJID XPSCAT VISITNUM XPTPT; /* 19) KB 15May2014 */
RUN;

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/* 14) START KB 14May2014 */
PROC SORT DATA=XPPPRESENT;
  BY USUBJID VISITNUM XPTPT;
RUN;

DATA XPPPRESENT2;
  SET XPPPRESENT;
  BY USUBJID VISITNUM XPTPT;

/*      IF INDEX(XPTPT,'UNSCHED') THEN DELETE;*/ /* 19) KB 15May2014 */
RUN;

PROC SORT DATA=XPPPRESENT2;
  BY USUBJID XPCAT VISITNUM XPTPT; /* 19) KB 15May2014 */
RUN;
/* 14) END KB 14May2014 */

DATA RATIO(DROP = FEV1 FVC PRESENT);
  MERGE /*XPPPRESENT*/XPPPRESENT2(WHERE = (XPTESTCD = 'FEV1MEAS' AND
PRESENT NE 1) RENAME = (XPSTRESN = FEV1)) /* 14) KB 14May2014 */
/*XPPPRESENT*/XPPPRESENT2(WHERE = (XPTESTCD = 'FVCMEAS' AND
PRESENT NE 1) RENAME = (XPSTRESN = FVC) KEEP = USUBJID XPCAT VISITNUM
XPTESTCD XPSTRESN PRESENT XPTPT); /* 14) KB 14May2014 */ /* 19) KB
15May2014 */
  BY USUBJID XPCAT VISITNUM XPTPT; /* 19) KB 15May2014 */
  XPTESTCD = 'DFEVFVC';
  XPTEST = 'Ratio between FEV1/FVC (Derived)';
  XPSTRESN = ROUND((FEV1 / FVC),0.01);
  XPSTRESC = LEFT(TRIM(PUT(XPSTRESN,5.2)));
  XPORRES = TRIM(XPSTRESC);
  XPORRESU = ' ';
  XPSTRESU = 'RATIO';
  XPSEQ=.;

RUN;
/* 7) END KB 30Apr2014 */

*****;
* Add to XP;
*****;

data xp2;
  set xp_ratio;
run;

*****;
* bring in XP ;
*****;
proc sort data = xp2;
  by usubjid xpseq;
run;

data xp3;
  merge xp2 suppxp2;

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by usubjid xpseq;
format paramcd $8. param $80. parcat1 avisit $40. avisitn paramn 8.
aval ATPTN best. avalc desc $200. avalu paramtyp dtype $20. /*ablfl $1.*/
adtm datetime13. /* 12) KB 15May2014 */ /* 22) KB 14Sep2014 */
      adt date9. ATPT $50.; /* 12) KB 15May2014 */

* parameters ;
if index(/*xpcat*/XPSCAT,'WITH ') then do; /* 8) KB 30Apr2014 */
    paramcd = 'W' || trim(compress(xptestcd,'1'));
    param = trim(xptest) || ' (with bronchodilator)';
end;
else do;
    paramcd = trim(compress(xptestcd,'1'));
    param = trim(xptest);
end;

if paramcd = 'WBRONCHO' then paramn = 1;
else if paramcd = 'WDOSE' then paramn = 2;
else if paramcd = 'WFVCPRED' then paramn = 3;
else if paramcd = 'WFVCMEAS' then paramn = 4;
else if paramcd = 'WFVCPCT' then paramn = 5;
else if paramcd = 'WFEVMEAS' then paramn = 6;
else if paramcd = 'WFEVPRED' then paramn = 7;
else if paramcd = 'WFEVPCT' then paramn = 8;
else if paramcd = 'WFEVFVC' then paramn = 9;
else if paramcd = 'WINTP' then paramn = 10;
else if paramcd = 'WFEVFC' then paramn = 11;
else if paramcd = 'FVCPRED' then paramn = 12;
else if paramcd = 'FVCMEAS' then paramn = 13;
else if paramcd = 'FVCPCT' then paramn = 14;
else if paramcd = 'FEVMEAS' then paramn = 15;
else if paramcd = 'FEVPRED' then paramn = 16;
else if paramcd = 'FEVPCT' then paramn = 17;
else if paramcd = 'FEVFVC' then paramn = 18;
/* else if paramcd = 'FEVFC' then paramn = 19; */
ELSE IF PARAMCD = 'DFEVFC' THEN PARAMN=20; /* 7) KB 30Apr2014 */
    else if paramcd = 'INTP' then paramn = 19;
ELSE IF PARAMCD='BRONCHO' THEN PARAMN=21; /* 10) KB 30Apr2014 */
ELSE IF PARAMCD='DOSE' THEN PARAMN=22; /* 10) KB 30Apr2014 */
ELSE IF PARAMCD='XPALL' THEN PARAMN=30; /* 9) KB 30Apr2014 */

parcat1 = trim(/*xpcat*/XPSCAT); /* 5) KB 30Apr2014 */
if xptestcd = /*'FEVFC'*/'DFEVFC' then do; /* 7) KB 30Apr2014 */
    paramtyp = 'DERIVED';
    dtype = 'RATIO';
end;

* analysis variables;
aval = xpstresn;
if xptestcd = 'INTP' then do;
    if index(xpstresc,'ABNORMAL') then do;
        DESCLEN = INDEX(XPSTRESC,'-'); /* 1) SM 03Dec2013 */
        avalc = propcase(scan(xpstresc,1,'-'));
    end;
end;

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desc = propcase(/*scan*/SUBSTR(xpstresc,DESCLEN+1/*2,'-
'*/),'.'); /* 1) SM 03Dec2013 */
DESC = TRANWRD(DESC,'Fvc','FVC'); /* 1) SM 03Dec2013 */
DESC = TRANWRD(DESC,'fev1/fvc','FEV1/FVC'); /* 1) SM
03Dec2013 */
DESC = TRANWRD(DESC,'fev1','FEV1'); /* 1) SM 03Dec2013
*/
DESC = TRANWRD(DESC,'Ae','AE'); /* 1) SM 03Dec2013 */
DESC = TRANWRD(DESC,'ae','AE'); /* 1) SM 03Dec2013 */
DESC = TRANWRD(DESC,'fvc','FVC'); /* 1) SM 03Dec2013 */
DESC=TRANWRD(DESC,'fev','FEV'); /* 16) KB 15May2014 */
end;
else avalc = propcase(xpstresc);
end;
else if xptestcd = 'BRONCHO' then avalc = propcase(xpstresc);
else avalc = trim(xpstresc);
avalu = trim(xpstresu);
/* 11) START KB 30Apr2014 */
/* ablf1 = xpblf1;*/
/* IF VISIT='DAY 0' AND XPSTAT NE 'NOT DONE' THEN ABLFL='Y'; */ /* 22)
KB 14Sep2014 */
/* 11) END KB 30Apr2014 */

* visit data;
avisit = propcase(visit);
avisitn = visitnum;

* dates;
length xpdtcl $19.;
xpdtcl=xpdtc;
if length(xpdtc) gt 10 then adtm = input(xpdtcl,e8601dt.);
if not missing(adtm) then adt=datepart(adtm);
else adt = input(xpdtc,ymmdd10.);

/*ATPT=STRIP(XPTPT);*/ /* 12) KB 15May2014 */
ATPT=STRIP(PROPCASE(XPTPT)); /* 14) KB 15May2014 */
ATPTN=XPTPTNUM; /* 12) KB 15May2014 */

keep usubjid xpclsig xpseq param: parcat1 xpmethod aval: /*ablf1*/
xpstat xpreasnd visit visitnum avisit: xpdtc xpdy adtm adt /* 22) KB
14Sep2014 */
paramtyp dtype desc EPOCH XPTPT ATPT;; /* 2) KB 30Apr2014 */ /*
14) KB 14May2014 */ /* 12) KB 15May2014 */
run;

*****;
* Calculate changes from baseline (D0) ;
*****;
/* 22) START KB 14Sep2014 */
DATA SV;
SET SDTM.SV(WHERE=(VISIT=('DAY 1')));
FORMAT DAY DATE9.;

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

DATA ABLFL;
    SET XP3(WHERE=(AVISIT IN ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day
1') AND XPSTAT NE 'NOT DONE'));

    KEEP USUBJID PARAMCD AVISIT ATPTN ADTM ATPT;
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 ADTM;
RUN;

DATA ABLFL3;
    SET ABLFL2A;

    IF TRT01A='SA' THEN DO;
        IF DAY NE . THEN DO;
            IF ADTM<DHMS(DAY,6,30,0) AND
INDEX(UPCASE(AVISIT),'UNSCHED')=0 AND INDEX(UPCASE(ATPT),'UNSCHED')=0
THEN ABLFL2='Y';
            END;
        ELSE IF DAY EQ . THEN DO;
            IF INDEX(UPCASE(AVISIT),'UNSCHED')=0 AND
INDEX(UPCASE(ATPT),'UNSCHED')=0 THEN ABLFL2='Y';
            END;
        END;
    ELSE IF TRT01A IN ('CC' 'THS 2.2') THEN DO;

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        IF ADTM<TRTSDTM AND INDEX(UPCASE(AVISIT),'UNSCHED')=0 AND
INDEX(UPCASE(ATPT),'UNSCHED')=0 THEN ABLFL2='Y';
        END;
        ELSE IF MISSING(TRT01A) THEN DO;
            IF INDEX(UPCASE(AVISIT),'UNSCHED')=0 AND
INDEX(UPCASE(ATPT),'UNSCHED')=0 THEN ABLFL2='Y';
            END;
RUN;

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

DATA ABLFL5(WHERE=(ABLFL='Y'));
    SET ABLFL4;
    BY USUBJID PARAMCD ADTM;
    FORMAT ABLFL $1.;

    IF LAST.PARAMCD THEN ABLFL='Y';

    KEEP USUBJID PARAMCD AVISIT ABLFL ATPTN;
RUN;

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

PROC SORT DATA=XP3;
    BY USUBJID PARAMCD AVISIT ATPTN;
RUN;

DATA XP3A;
    MERGE XP3 ABLFL5;
    BY USUBJID PARAMCD AVISIT ATPTN;
RUN;

/* 14) START KB 14May2014 */
/*PROC SORT DATA=XP3;*/
/*    BY USUBJID PARAMN AVISITN XPTPT;*/
/*RUN;*/
/**/
/*DATA XP3A;*/
/*    SET XP3(WHERE=(AVISIT='Day 0' AND INDEX(XPTPT,'UNSCHE')=0)); */
/*    BY USUBJID PARAMN AVISITN XPTPT;*/
/**/
/*    IF FIRST.PARAMN AND FIRST.XPTPT THEN ABLFL2='Y'; */
/*    KEEP USUBJID PARAMN AVISITN XPTPT ABLFL2;*/
/*RUN;*/
/**/
/*PROC SORT DATA=XP3A(WHERE=(ABLFL2='Y'));*/
/*    BY USUBJID PARAMN AVISITN XPTPT;*/
/*RUN;*/
/**/
/*DATA XP3B;*/

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/*      MERGE XP3 XP3A;*/
/*      BY USUBJID PARAMN AVISITN XPTPT;*/
/**/
/*      IF ABLFL='Y' AND ABLFL2='' THEN ABLFL='';*/
/*      DROP ABLFL2;*/
/*RUN;*/
/* 14) END KB 14May2014 */
/* 22) END KB 14Sep2014 */

proc sort data = /*xp3*//*XP3B*/XP3A; /* 14) KB 14May2014 */ /* 22) KB
14Sep2014 */
    by usubjid paramn avisitn;
run;

* baseline ;
data base;
    set /*xp3*//*XP3B*/XP3A(where = (ablfl = 'Y')); * check SDTM.XP
has VSBLFL correct to SAP ; /* 14) KB 14May2014 */ /* 22) KB 14Sep2014 */
    format base best. basec $200.;
    base = aval;
    basec = avalc;
    bvis = /*visitnum*/ATPTN; * keep to make sure only calculate
change after baseline ; /* 20) KB 15May2014 */
    BXPCLSIG=XPCLSIG; /* 23) KB 14Sep2014 */

    keep usubjid paramn base basec bvis BXPCLSIG; /* 23) KB 14Sep2014
*/
run;

/* 22) START KB 14Sep2014 */
PROC SORT DATA=XP3A;
    BY USUBJID PARAMN;
RUN;

PROC SORT DATA=BASE;
    BY USUBJID PARAMN;
RUN;
/* 22) END KB 14Sep2014 */

* change ;
data change(drop = bvis BXPCLSIG); /* 23) KB 14Sep2014 */
    merge /*xp3*//*XP3B*/XP3A base; /* 14) KB 14May2014 */ /* 22) KB
14Sep2014 */
    by usubjid paramn;
    format chg best. shift1 $50.;
    if /*avisitn*/ATPTN gt bvis then do; /* 20) KB 15May2014 */
/*      chg = aval - base;*/
        CHG=ROUND(AVAL-BASE,0.0000000001); /* 13) KB 15May2014 */
/* 18) START KB 15May2014 */
        IF NOT MISSING(AVALC) AND PARAMCD='INTP' THEN DO; /* 23) KB
14Sep2014 */
/* 23) START KB 14Sep2014 */
/*      if paramcd = 'INTP' then shift1 = trim(basec) || ' to '
||trim(avalc);*/

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        IF NOT MISSING(BXPCLSIG) AND NOT MISSING(XPCLSIG) THEN SHIFT1
= TRIM(BASEC) || ', ' || STRIP(BXPCLSIG) || ' to ' || TRIM(AVALC) || ', '
|| STRIP(XPCLSIG);
        ELSE IF NOT MISSING(BXPCLSIG) AND MISSING(XPCLSIG) THEN
SHIFT1=TRIM(BASEC) || ', ' || STRIP(BXPCLSIG) || ' to ' || TRIM(AVALC);
        ELSE IF MISSING(BXPCLSIG) AND NOT MISSING(XPCLSIG) THEN
SHIFT1=TRIM(BASEC) || ' to ' || TRIM(AVALC) || ', ' || STRIP(XPCLSIG);
        ELSE IF MISSING(BXPCLSIG) AND MISSING(XPCLSIG) THEN
SHIFT1=TRIM(BASEC) || ' to ' || TRIM(AVALC);
/* 23) END KB 14Sep2014 */
        END;
/* 18) END KB 15May2014 */
        end;
run;

proc sort data=change;
    by usubjid paramn parcat1 avisitn;
run;

data change2;
    set change;
    by usubjid paramn parcat1 avisitn;
    * determine if any unscheduled;
    format anl01fl $2.;
    if /*avisit = 'UNSCHEDULED'*/INDEX(UPCASE(AVISIT),'UNSCHED') OR
INDEX(UPCASE(ATPT),'UNSCHED') or paramcd = 'XPALL' OR XPSTAT='NOT DONE'
then anl01fl = ' '; /* 6) KB 30Apr2014 */ /* 17) KB 15May2014 */
    else if last.parcat1 and first.avisitn = 0 then anl01fl = ' ';
    else anl01fl = 'Y';
    if anl01fl = ' ' then put 'Check reason for exclusion from
analysis: ' usubjid = param = avisit = ;
run;

*****;
* Combine ADSL and XP data *;
*****;
* find periods;
%_mtotper;

data slxp(drop = trt01: tr01: visit:);
    merge adsl change2(in = a);
    by usubjid;
    if a;          * only include subject level data in vital signs ;
    format aperiod trtan trtpn aday 8. trta trtp $40. aperiodc $10.;
    aday = adt - trtsdt + 1;
    * allocate period / treatment;
    %_mperall(dvar1 = adtm, dvar2 = adt);
    aperiodc = 'Period ' || put(aperiod, 1.);

/* 15) START KB 15May2014 */
    IF PARAMCD='DFEVFVC' THEN DO;
        XPDTTC='';
        XPDY=.;
        EPOCH='';

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        END;
/* 15) END KB 15May2014 */
        DROP XPTPT; /* 14) KB 14May2014 */
run;

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

options replace;

data adxp;
    set stdlib.adxp slxp;
run;

proc sort data = adxp out = adam.adxp(label = 'Pulmonary Function
Analysis Dataset');
/*    by usubjid avisitn paramcd;*/
    BY USUBJID AVISITN ATPTN PARAMCD; /* 12) KB 14May2014 */
run;

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

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