

```

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 : 000000106326;
%put NOTE: Client Protocol ID : ZRHM-PK-05-JP;
%put NOTE: Program Name : d_2ADPC.sas;
%put NOTE: Purpose : create ADPC dataset;
%put NOTE: ;
%put NOTE: Input Data : STDLIB.ADPC SDTM.PC ADAM.PKMERGE
ADAM.ADSL SDTM.SV SOURCE\BIOA\SSO.XPT;
%put NOTE: Output : ADAM.ADPC;
%put NOTE: Macros Called : _MPRINTTO _MTOTPER _MPERALL;
%put NOTE: ;
%put NOTE: Programmed by : cvn_kbooth;
%put NOTE: Creation Date : 2014-04-22;
%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: 23Apr2014 KB 1) Given formats to ATPT ATPTN AVISIT
AVISITN;
%put NOTE: 23Apr2014 KB 2) Amended PNOMTIME to be in minutes;
%put NOTE: 23Apr2014 KB 3) Amended derivation of AVAL;
%put NOTE: 03Jun2014 SM 4) amend code to include updated data
post lock also 04Jun2014;
%put NOTE: 04Jun2014 SM 5) Amend label for NEND12;
%put NOTE: 6) Amend code for AEXREAS to exclude
start and end points;
%put NOTE: 07Aug2014 KB 7) Added merged ADPC macro;
%put NOTE: 07Aug2014 KB 8) Added duplication of BLQ data;
%put NOTE: 07Aug2014 KB 9) Amended sorting by key variables;
%put NOTE: 08Aug2014 KB 10) AMended format to best32.;
%put NOTE: 08Aug2014 KB 11) AMended PARA & AVALU;
%put NOTE: 08Aug2014 KB 12) AMended ANL01FL;
%put NOTE: 08Aug2014 KB 13) Added ATMF;
%put NOTE: 08Aug2014 KB 14) Amended formats;
%put NOTE: 08Aug2014 KB 15) Amended warnings in log;
%put NOTE: 21Sep2014 KB 16) Amended format of DEVN;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;

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ods listing;

*=====;
* START OF PROGRAM CODE ;
*=====;

%_MERGEADPC; /* 7) KB 07Aug2014 */

* pull in start and end points;
* libname sets up which xpt file data is contained in - provided by pk
group;
* if there is not regression analysis then this section is not required;
libname xpt xport
"/cvn/projects/prj/data/000000106326/source/bioa/sso.xpt";

* read in xpt file to work.sas ;
proc copy in=xpt out=work memtype=data;
run;

*clear libname xpt;
libname xpt;
options noreplace;

*select subset of required data;
data sten;
    * lambdaz denotes which points are included ;
    set sas(where=(not missing(lambdaz)));
    FORMAT ADAY 8.; /* 14) KB 08Aug2014 */

    * set up missing variables to identify period/dosing day for ADPC;
    *may not be required once full data provided;

    pactime=pkdactim/60; /* 4) SM 04Jun2014 */

    if aday in (1 2) then aperiod=1;
    else if aday in (3 4) then aperiod=2;
    drop param: trt: studyid usubjid weightbl lambdaz pklevel residual
auc aumc weight;
run;

proc sort data=sten;
    by subjidn aperiod pactime;
run;

data sten2;
    set sten;
    by subjidn aperiod;
    format paramcd $8. paramn 8. aval /*best.*/BEST32. param $120. avalc
$20. units $20.; /* 10) KB 08Aug2014 */
    if first.aperiod then do;
        paramcd='NSTART';
        paramn=3;
/*          param='Start of Elimination Phase for Nicotine (h)';*/

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        PARAM='Predicted Concentration at Start of Elimination Phase for
Nicotine (ng/mL)'; /* 11) KB 08Aug2014 */
/* 10) START KB 08Aug2014 */
/*      aval=pred;*/
/*      avalc=left(put(pred,best.)); */
        AVALC=STRIP(PRED);
        AVAL=INPUT(AVALC,BEST32.);
/* 10) END KB 08Aug2014 */
/*      units='h';*/
        UNITS='ng/mL'; /* 11) KB 08Aug2014 */
        output;
    end;
    if last.aperiod then do;
        paramcd='NEND';
        paramn=4;
/*      param='End of Elimination Phase for Nicotine (h)';*/
        PARAM='Predicted Concentration at End of Elimination Phase for
Nicotine (ng/mL)'; /* 11) KB 08Aug2014 */
/* 10) START KB 08Aug2014 */
/*      aval=pred;*/
/*      avalc=left(put(pred,best.)); */
        AVALC=STRIP(PRED);
        AVAL=INPUT(AVALC,BEST32.);
/* 10) END KB 08Aug2014 */
/*      units='h';*/
        UNITS='ng/mL'; /* 11) KB 08Aug2014 */
        output;
    end;
    drop pred;
run;

/* NEW BLOCK 4) SM 03Jun2014 */
libname xpt xport
"/cvn/projects/prj/data/000000106326/source/bioa/ssol2.xpt";

* read in xpt file to work.sas ;
proc copy in=xpt out=work memtype=data;
run;

*clear libname xpt;
libname xpt;
options noreplace;

*select subset of required data;
data sten12;
    * lambdaz denotes which points are included ;
    set sas(where=(not missing(lambdaz)));

    * set up missing variables to identify period/dosing day for ADPC;
    *may not be required once full data provided;

    pactime=pkdactim/60; /* 4) SM 04Jun2014 */

    if aday in (1 2) then aperiod=1;

```

```

        else if aday in (3 4) then aperiod=2;
        drop param: trt: studyid usubjid weightbl lambdaz pklevel residual
auc aumc weight;
run;

proc sort data=sten12;
    by subjidn aperiod pactime;
run;

data sten2A;
    set sten12;
    by subjidn aperiod;
    format paramcd $8. paramn 8. aval /*best.*/BEST32. param $120. avalc
$20. units $20.; /* 10) KB 08Aug2014 */
    if first.aperiod then do;
        paramcd='NSTART12';
        paramn=5;
/*
        param='Start of 0-12 h Elimination Phase for Nicotine (h)';*/
        PARAM='Predicted Concentration at Start of 0-12 h Elimination
Phase for Nicotine (ng/mL)'; /* 11) KB 08Aug2014 */
/* 10) START KB 08Aug2014 */
/*
        aval=pred;*/
/*
        avalc=left(put(pred,best.));*/
        AVALC=STRIP(PRED);
        AVAL=INPUT(AVALC,BEST32.);
/* 10) END KB 08Aug2014 */
/*
        units='h';*/
        UNITS='ng/mL'; /* 11) KB 08Aug2014 */
        output;
    end;
    if last.aperiod then do;
        paramcd='NEND12';
        paramn=6;
/*
        param='End of 0-12 h Elimination Phase for Nicotine (h)'; *//*
5) SM 04Jun2014 */
        PARAM='Predicted Concentration at End of 0-12 h Elimination Phase
for Nicotine (ng/mL)'; /* 11) KB 08Aug2014 */
/* 10) START KB 08Aug2014 */
/*
        aval=pred;*/
/*
        avalc=left(put(pred,best.));*/
        AVALC=STRIP(PRED);
        AVAL=INPUT(AVALC,BEST32.);
/* 10) END KB 08Aug2014 */
/*
        units='h';*/
        UNITS='ng/mL';
        output;
    end;
    drop pred;
run;
/* END OF NEW BLOCK 4) SM 03Jun2014 */

* pull in pkmerge data;
* for some studies this will contain only a subset of the data please
check SAP;

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data /*pkmerge*/PKMERGE2; /* 7) KB 07Aug2014 */
  set /*adam.*/pkmerge; /* 7) KB 07Aug2014 */
  LENGTH PCRESND2 $29 PCDTC2 $16; /* 15) KB 08Aug2014 */

  *AVAL=PKLEVEL; /* 3) KB 23Apr2014 */ /* NO LONGER REQUIRED 4) SM
03Jun2014 */

  PCRESND2=PCREASND; /* 15) KB 08Aug2014 */
  PCDTC2=PCDTC; /* 15) KB 08Aug2014 */

  RENAME PCRESND2=PCREASND; /* 15) KB 08Aug2014 */
  RENAME PCDTC2=PCDTC; /* 15) KB 08Aug2014 */

  drop studyid usubjid siteid weightbl nicdose nicu exdose exdosu trtan
trtp: trtseq: PCREASND PCDTC; /* 15) KB 08Aug2014 */
run;

* further code will be required to include cotinine data from SDTM.PC for
other studies;
* include here and then add into adpcl below;

data adpcl;
  set /*pkmerge*/PKMERGE2 sten2 STEN2A; /* 4) SM 04Jun2014 */ /* 7) KB
07Aug2014 */
  format pnomtime best. avalu $20. ATPT $200. AVISIT $40. ATPTN AVISITN
/*DEVN*/ /*BEST.*/8. DEVN BEST.; /* 1) KB 23Apr2014 */ /* 14) KB
08Aug2014 */ /* 16) KB 21Sep2014 */
  pnomtime=ntime; /* uncommented 4) SM 04Jun2014 */
  *PNOMTIME=ROUND(NTIME*60,1.); /* 2) KB 23Apr2014 */ /* 4) SM
04Jun2014 */
  avalu=trim(units);
  format devwc /*$10.*/$15.; /* 14) KB 08Aug2014 */
  *character deviation from window;
  * study specific code - please check;
  if not missing(devn) then do;
    if atpt='15 min < T0' and not (-15 le devn le 0) then do;
      if devn lt -15 then devwc=compress(put(devn+15,best.))||'
min';
    else if devn gt 0 then
devwc='+'||compress(put(devn,best.))||' min';
    end;
    else if atpt='T0 + 60 min' and not (0 le devn le 3) then do;
      if not missing(devn) and devn lt 0 then
devwc=compress(put(devn,best.))||' min';
      else if devn gt 3 then devwc='+'||compress(put(devn-
3,best.))||' min';
    end;
    else if atpt in ('T0 + 2 h' 'T0 + 3 h' 'T0 + 4 h' 'T0 + 6 h' 'T0
+ 9 h' 'T0 + 12 h' 'T0 + 24 h')
      and not (0 le devn le 5) then do;
      if not missing(devn) and devn lt 0 then
devwc=compress(put(devn,best.))||' min';
      else if devn gt 5 then devwc='+'||compress(put(devn-
5,best.))||' min';

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        end;
        else if (trta='NRT gum' and atpt in ('T0 + 10 min' 'T0 + 20 min'
'T0 + 25 min' 'T0 + 30 min' 'T0 + 35 min'
'T0 + 40 min' 'T0 + 45 min')) or
        (trta ne 'NRT gum' and atpt in ('T0 + 2 min' 'T0 + 4 min' 'T0 + 6
min' 'T0 + 8 min' 'T0 + 10 min'))
        and not (0 le devn le 1) then do;
            if not missing(devn) and devn lt 0 then
devwc=compress(put(devn,best.))||' min';
            else if devn gt 1 then devwc='+'||compress(put(devn-
1,best.))||' min';
            end;
            else if atpt in ('T0 + 15 min' 'T0 + 30 min' 'T0 + 45 min') and
not (0 le devn le 2) then do;
                if not missing(devn) and devn lt 0 then
devwc=compress(put(devn,best.))||' min';
                else if devn gt 2 then devwc='+'||compress(put(devn-
2,best.))||' min';
                end;
            end;
        end;
run;

data adpc2;
    set adpc1;
    format /*anl01fl*/ANL01FL blqfl $2. /*aexreas $200.*/; /* 4) SM
04Jun2014 */ /* 12) KB 08Aug2014 */
    *if paramcd='NIC' then anl01fl='Y'; * to be amended after
data review by client; /* MOVED BELOW 4) SM 04Jun2014 */

    *aexreas=''; * to be completed after review of data; /*
moved below 4) SM 04Jun2014 */
    blqfl=blqfl;
    * dates;
    format adt date9. atm time8. adtm datetime16. ATMF $1.; /* 13) KB
08Aug2014 */
    IF LENGTH(SCAN(PCDTC,2,'T'))=5 THEN DO; /* 13) KB 08Aug2014 */
        PCDTC2=CATS(PCDTC,':30');
/* if not missing(pcdtc) then adtm=input(pcdtc,e8601dt.);*/
        IF NOT MISSING(PCDTC2) THEN
ADTM=DHMS(INPUT(SCAN(PCDTC2,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(PCDTC2,2,'T'
'),TIME8.)),MINUTE(INPUT(SCAN(PCDTC,2,'T'),TIME8.)),SECOND(INPUT(SCAN(PCD
TC2,2,'T'),TIME8.)))); /* 15) KB 08Aug2014 */
        adt=datepart(adtm);
        atm=timepart(adtm);
        ATMF = 'S'; /* 13) KB 08Aug2014 */
    END; /* 13) KB 08Aug2014 */
/* 13) START KB 08Aug2014 */
    ELSE IF LENGTH(SCAN(PCDTC,2,'T'))=8 THEN DO;
        IF NOT MISSING(PCDTC) THEN
ADTM=DHMS(INPUT(SCAN(PCDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(PCDTC,2,'T')
,TIME8.)),MINUTE(INPUT(SCAN(PCDTC,2,'T'),TIME8.)),SECOND(INPUT(SCAN(PCDTC
,2,'T'),TIME8.))));
        ADT=DATEPART(ADTM);
        ATM=TIMEPART(ADTM);

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        END;
/* 13) END KB 08Aug2014 */

        IF PARAMCD='NIC' THEN ANL01FL='Y'; /* 12) KB 08Aug2014 */
        DROP PCDT2; /* 13) KB 08Aug2014 */
run;

/* 8) START KB 07Aug2014 */
DATA DUPLIT_;
    SET ADPC2;
    WHERE BLOQFL='Y';
    FORMAT DTYPE $20.;
    IF MISSING(AVAL) THEN DO;
        AVAL = .;
        AVALC='BLQ';
        DTYPE='BLQNULL';
        AQLFL = 'Y';
    END;
    ELSE IF ATPTN=0 THEN DO;
        AVAL = 0;
        AVALC=COMPRESS(PUT(AVAL,BEST.));
        DTYPE='BLQZERO';
        AQLFL = 'Y';
    END;
    ELSE IF ATPTN>0 THEN DO;
        AVAL = 0.5 * PCLLOQ;
        AVALC=COMPRESS(PUT(AVAL,BEST.));
        DTYPE='BLQHALF';
        AQLFL = 'Y';
    END;
    DROP PCLLOQ PCSEQ PCDTC PCSPEC PCORRES;
RUN;

DATA ADPC3A;
    SET ADPC2(in=a) DUPLIT_;
    IF a and AVALC='BLQ' THEN call missing (AVAL, ANL01FL); /* 12) KB
08Aug2014 */
RUN;
/* 8) END KB 07Aug2014 */

proc sort data=/*adpc2*/ADPC3A; /* 8) KB 07Aug2014 */
    by subjidn pcseq;
run;

* bring in pc data for day ;
data pc;
    set sdtm.pc;

    format subjidn 8.;
    subjidn=input(scan(usubjid,6,'-'),best.);
    keep pcseq pcdy subjidn epoch;
run;

proc sort data=pc;

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        by subjidn pcseq;
run;

data adpc3;
    merge /*adpc2*/ADPC3A pc; /* 8) KB 07Aug2014 */
    by subjidn pcseq;
run;

*bring in screening date;
data sv;
    set sdtm.sv(where=(visit='SCREENING'));
    format scrndt date9.;
    scrndt=input(svstdtc, yymmdd10.);
    format subjidn 8.;
    subjidn=input(scan(usubjid,6,'-'),best.);
    keep usubjid scrndt subjidn;
run;

* bring in adsl for T0 and subject level data;
data adsl;
    merge adam.adsl adpc3(in=a) sv;
    by subjidn;
    if a;
    FORMAT ANL01FL $2. AEXREAS $200.; /* 4) SM 04Jun2014 */
/* 12) START KB 08Aug2014 */
/* IF PARAMCD='NIC' THEN DO; *//* 6) SM 04Jun2014 */
/* IF PPROTFL='Y' THEN ANL01FL='Y'; */ /* 4) SM 04Jun2014 */ /*
6) SM 04Jun2014 */
/* AEXREAS=TRIM(PPREAS); */ /* 4) SM 04Jun2014 */
/* END; *//* 6) SM 04Jun2014 */
/* 12) END KB 08Aug2014 */
    format aperiodc $8.;
    aperiodc='Period '||compress(put(aperiod,1.));

    format trta trtp $40. trtan trtpn 8.;

    if aperiod=1 then do;
        trta=trt01a;
        trtp=trt01p;
        trtan=trt01an;
        trtpn=trt01pn;
    end;
    else if aperiod=2 then do;
        trta=trt02a;
        trtp=trt02p;
        trtan=trt02an;
        trtpn=trt02pn;
    end;

/* 12) START KB 08Aug2014 */
    IF PPROTFL='N' THEN DO;
        ANL01FL=' ';
        AEXREAS=PPREAS;
    END;

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/* 12) END KB 08Aug2014 */

/*IF DTYPE NE '' THEN ANL01FL='';*/ /* 8) KB 07Aug2014 */
run;

data adpc4;
  set adsl;
  * windows;
  if aperiod=1 and not missing(tr01sdtm) then trtstart=tr01sdtm;
  else if aperiod=2 and not missing(tr02sdtm) then trtstart=tr02sdtm;
  format awlo awhi datetime16. awrange $50.;
  if not missing(trtstart) and paramcd not in ('NSTART' 'NEND'
'NSTART12' 'NEND12') then do; /* 4) SM 04Jun2014 */
    if atptn=0 then do;
      awlo=trtstart-'00:15:00't;
      awhi=trtstart;
    end;
    else if atptn=1 then do; /* 2 min */
      awlo=trtstart+'00:02:00't;
      awhi=trtstart+'00:03:00't;
    end;
    else if atptn=2 then do; /* 4 min */
      awlo=trtstart+'00:04:00't;
      awhi=trtstart+'00:05:00't;
    end;
    else if atptn=3 then do; /* 6 min */
      awlo=trtstart+'00:06:00't;
      awhi=trtstart+'00:07:00't;
    end;
    else if atptn=4 then do; /* 8 min */
      awlo=trtstart+'00:08:00't;
      awhi=trtstart+'00:09:00't;
    end;
    else if atptn=5 then do; /* 10 min */
      awlo=trtstart+'00:10:00't;
      awhi=trtstart+'00:11:00't;
    end;
    else if atptn=6 then do; /* 15 min */
      awlo=trtstart+'00:15:00't;
      awhi=trtstart+'00:17:00't;
    end;
    else if atptn=7 then do; /* 20 min */
      awlo=trtstart+'00:20:00't;
      awhi=trtstart+'00:21:00't;
    end;
    else if atptn=8 then do; /* 25 min */
      awlo=trtstart+'00:25:00't;
      awhi=trtstart+'00:26:00't;
    end;
    else if atptn=9 and trta='NRT gum' then do; /* 30 min nrt gum*/
      awlo=trtstart+'00:30:00't;
      awhi=trtstart+'00:31:00't;
    end;
    else if atptn=9 then do; /* 30 min ths/cc*/

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        awlo=trtstart+'00:30:00't;
        awhi=trtstart+'00:32:00't;
    end;
    else if atptn=10 then do; /* 35 min */
        awlo=trtstart+'00:35:00't;
        awhi=trtstart+'00:36:00't;
    end;
    else if atptn=11 and trta='NRT gum' then do; /* 40 min*/
        awlo=trtstart+'00:40:00't;
        awhi=trtstart+'00:41:00't;
    end;
    else if atptn=12 and trta='NRT gum' then do; /* 45 min nrt gum*/
        awlo=trtstart+'00:45:00't;
        awhi=trtstart+'00:46:00't;
    end;
    else if atptn=12 then do; /* 45 min ths/cc*/
        awlo=trtstart+'00:45:00't;
        awhi=trtstart+'00:47:00't;
    end;
    else if atptn=13 then do;
        awlo=trtstart+'01:00:00't; /* 4) sm 26mar2014 */
        awhi=trtstart+'01:03:00't; /* 4) sm 26mar2014 */
    end;
    else if atptn=14 then do; /* 2 h */
        awlo=trtstart+'02:00:00't;
        awhi=trtstart+'02:05:00't;
    end;
    else if atptn=15 then do; /* 3 h */
        awlo=trtstart+'03:00:00't;
        awhi=trtstart+'03:05:00't;
    end;
    else if atptn=16 then do; /* 4 h */
        awlo=trtstart+'04:00:00't;
        awhi=trtstart+'04:05:00't;
    end;
    else if atptn=17 then do; /* 6 h */
        awlo=trtstart+'06:00:00't;
        awhi=trtstart+'06:05:00't;
    end;
    else if atptn=18 then do; /* 9 h */
        awlo=trtstart+'09:00:00't;
        awhi=trtstart+'09:05:00't;
    end;
    else if atptn=19 then do; /* 12 h */
        awlo=trtstart+'12:00:00't;
        awhi=trtstart+'12:05:00't;
    end;
    else if atptn=20 then do; /* 24 h */
        awlo=trtstart+'24:00:00't;
        awhi=trtstart+'24:05:00't;
    end;
end;
end;
    if not missing(awlo) then awrange=put(awlo,datetime16.) || '-
'||put(awhi,datetime16.);

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run;

proc sql noprint;
    select name into: keepvars separated by " " from sashelp.vcolumn
where libname = "STDLIB" and memname = "ADPC";
quit;

options replace;

data adpc;
    set stdlib.adpc adpc4;
    keep &keepvars;
run;

proc sort data = adpc out = adam.adpc(label= 'Pharmacokinetic
Concentration Analysis Dataset');
/*    by usubjid aperiod avisitn paramcd atptn;*/
    BY USUBJID APERIOD AVISITN PARAMCD ATPTN DTYPE; /* 9) KB 07Aug2014 */
run;

options noreplace;
%_scramble(set=adpc, id=usubjid subjid subjidn age sex sexc sexn race
dthfl height weightbl bmi ucpdgr1 ucpdgrln nicogr1
        nicogrln targr1 targrln analgr1 analgrln, dates=atpt
atptn avisit avisitn pkday pnomtime pactime devn devwc pctdev
        awrange awlo awhi pcdtc pcdy adt atm adtm atmf aday
aperiod aperiodc epoch,
        nullc=trtstmf tr01stmf tr02stmf trtp trta trtseqp trtseqa ,
        nulln= trtsdtm trtsdt trtsday trtedtm trtedt trteday tr01sdt
tr01stm tr01sdtm tr01edt tr01etm tr01edtm tr02sdt tr02stm tr02sdtm
        tr02edt tr02etm tr02edtm trtseqpn trtseqan trtpn trtan,
nullcc=7, nullnc=22);

proc printto; run;
*=====;
* END OF PROGRAM CODE                                ;
*=====;
```