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Covance Study ID : COV-000000106343

Program Name : d\_2adpc.sas

Purpose : Program to create ADQSPA dataset

Author : cvn\_pshe

Date of Creation : 3MAY2015

Input Data : ADAM.ADSL,SDTM.PC,SDTM.EX,SDTM.SV

Output Data : ADAM.ADQSPA

Macros Called : m\_printto,, m\_logchk, m\_attrib\_adam

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Modification History  
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Modified by :

Modification Date :

Modification Description:

-----\*/

options notes nosource;

proc datasets lib=work nolist memtype=data kill; quit;

\* macro to save output and log to appropriate areas ;

%m\_printto;

options notes source source2 nofullstimer validvarname=upcase missing=' ' mprint symbolgen;

ods \_all\_ close;

ods listing;

```

*=====;

* START OF PROGRAM CODE                                ;

*=====;

* pull in pkmerge data;

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


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

libname sdtm "/cvn/projects/prj/data/000000106343/datasets/sdtm/sdtmx";


data pkmerge;

    set adam.pkmerge;

    format avalu $20.;


    *test date and time;

    format adt date9. atm time5. adtm datetime13.;

    if not missing(pcdtc) and length(pcdtc) >=10 then adt=input(scan(pcdtc,1,'T'),yymmdd10.);

    atm=input(scan(pcdtc,2,'T'),time8.);

        if nmiss(adtm,atm) =0 then adtm=dhms(adtm, 0,0,atm);

    if avisit='Day 6' then avisit='Day 6/Discharge';

        avalu=trim(units);

    drop siteid weightbl exdose exdosu trta: trtp: aday pcorres ;

run;


%m_chglength(inds=pkmerge,varlist=avalc, lenlist=$200);

```

\* further code will be required to include data from SDTM.PC for other studies;

\* identify SA arm subjects;

data sa;

set adam.adsl(where=(armcd='SMABST'));

keep usubjid;

run;

\*pick up data not used in PKmerge;

data pc;

merge sdtm.pc(in=b) sa(in=a);

by usubjid;

if a then sa=1;

if b;

format avalc \$200. aval best. avalu \$20. param \$120. paramcd \$3. paramn subjdn 8.;

subjdn=input(scan(usubjid,6,'-'),best.);

\*results;

aval=pcstresn;

avalc=pcstresc;

avalu=pcstresu;

\*parameter category;

```

        if pctestcd ne " then do;

if not missing(pcstresu) and pctest ne " then param=trim(pctest) || ' (' || trim(pcstresu) || ')';

else if pctestcd='COT' then param='Cotinine (ng/mL)';

                                else if pctestcd='NIC' then param='Nicotine (ng/mL)';

paramcd=pctestcd;

                                end;


if pctestcd='NIC' then

    paramn=1;

else if pctestcd='COT' then

    paramn=2;

else put 'PCTEST not recognised : ' pctestcd;


*treatment period;

format aperiod 8.;

aperiod=1;


format adt date9. atm time5. adtm datetime13.;

if not missing(pcdtc) and length(pcdtc) >=10 then adt=input(scan(pcdtc,1,'T'),yymmdd10.);

atm=input(scan(pcdtc,2,'T'),time8.);

                                if nmiss(adtm)=0 then adtm=dhms(adtm, 0,0,atm);


*visits and timepoints;

format avisit atpt $40. avisitn atptn 8.;

avisit=propcase(visit);

```

```
avisitn=visitnum;
```

```
if avisit in ('Day 0' 'Day 1' 'Day 2' 'Day 3' 'Day 4') then do;
```

```
    atpt='08:00 PM - 09:30 PM';
```

```
        atptn=11;
```

```
    end;
```

```
if avisit in ('Day 30' 'Day 60') then do;
```

```
    atpt='10:00 AM - 11:30 AM';
```

```
        atptn=12;
```

```
    end;
```

```
if avisit in ('Day 90') then do;
```

```
    atpt='10:00 AM - 12:30 PM';
```

```
        atptn=13;
```

```
    end;
```

```
if sa=1 and avisit ='Day 5' then do; atpt='08:00 PM - 09:30 PM';  
atptn=11; end;
```

```
else if sa=1 and avisit ='Day 6/Discharge Confinement' then do;  
atpt='08:00 AM - 09:30 AM'; atptn=14; end;
```

```
keep usubjid subjidn pcseq pcspec pcstat pcreasnd param: avisit: atpt: aperiod aval avalc avalu pcdtc  
adt atm adtm
```

```
pcorres pcloq sa;
```

```
if a then output; * SA data not included in pkmerge;
```

```
    else if not a and not(avisit in ('Day 5', 'Day 6/Discharge Confinement')) then output; * all other data  
    not in Day 5 and Day 6;
```

```
run;
```

```
* set all and populated PCLLOQ***;
```

```
data adpc;
```

```
    set pkmerge pc;
```

```
    format dtype $20. ;
```

```
    rename ntime = pnomtime;
```

```
    format ablfl $2.;
```

```
    if avisit='Day 0' and aval ne . then ablfl='Y';
```

```
                if index(avalc,'BLQ') then do;
```

```
                    aval=.;
```

```
                                dtype=' ';
```

```
                                bloqfl='Y';
```

```
                                pcloq = input(scan(avalc, 2, '< ( )'), best.);
```

```
    end;
```

```
run;
```

```
* derive bloqfl and imputed records;
```

```
data blq;
```

```
    set adpc;
```

```
    format bloqfl $2.;
```

```
    if index(avalc,'BLQ');
```

```
        aval=pcloq/2;
```

```
        avalc=strip(put(aval, best.));
```

```
dtype='BLQHALF';
```

```
bloqfl='Y';
```

```
run;
```

```
data adpc;
```

```
set adpc blq;
```

```
run;
```

```
proc sort data=adpc;
```

```
by usubjid subjidn pcseq;
```

```
run;
```

```
* bring in pc data for day ;
```

```
data pca;
```

```
set sdtm.pc;
```

```
format subjidn 8.;
```

```
subjidn=input(scan(usubjid,6,'-'),best.);
```

```
keep usubjid pcseq pcdy subjidn epoch;
```

```
run;
```

```
proc sort data=pca;
```

```
by usubjid subjidn pcseq;
```

```
run;
```

```
data adpc;
```

```
merge pca adpc (in=a);  
by usubjid subjidn pcseq;  
if a;  
run;  
  
*bring in screening date;  
data sv;  
set sdtm.sv(where=(visit='SCREENING'));  
format scrndt date9.;  
scrndt=input(svstdtc,yyymmdd10.);  
format subjidn 8.;  
subjidn=input(scan(usubjid,6,'-'),best.);  
keep usubjid scrndt subjidn;  
run;  
  
proc sort data=adam.adsl out=adsl;  
by usubjid subjidn;  
run;  
  
proc sort data=sv;  
by usubjid subjidn;  
run;  
  
* bring in adsl for T0 and subject level data;  
data adsl;
```



```
merge adsl adpc(in=a) sv;
```

```
by usubjid subjidn;
```

```
if a;
```

```
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;
```

```
run;
```

```
*need first product use dates and times;
```

```
*included all so that there is needed;
```

```
data ex;
```

```
set adam.adex;
```

```
if astday ge 0;
```

```
keep usubjid astdt astdtm astday;
```

```
run;
```

```
proc sort data=ex;

  where astdtm ne .;

  by usubjid astday astdtm;

run;
```

```
data ex;

  set ex;

  by usubjid astday;

  if first.astday;

run;
```

```
proc transpose data=ex out=texdx prefix=tr;

  var astdtm;

  by usubjid;

  id astday;

run;
```

```
* windows;

data adpc2;

  format awlo awhi datetime13. awrange $50. aday 8.; ;

  merge adsl(in=a) texdx;

  by usubjid;

  if a;

  if nmiss(adl, trtsdt)=0 then aday=adl-trtsdt+1;
```

```
        if trta in ('THSm2.2', 'mCC') and not missing(tr5) then trtstart=tr5;  
/*specific for REXC where pkday = day 5*/
```

```
    if nmiss(adt)=0 then do;
```

```
        if avisit in ('Day 0', 'Day 1', 'Day 2', 'Day 3', 'Day 4') then do;
```

```
            awlo=adt*24*60*60+'20:00't;
```

```
                awhi=adt*24*60*60+'21:30't;
```

```
        end;
```

```
        else if avisit in ('Day 30', 'Day 60') then do;
```

```
            awlo=adt*24*60*60+'10:00't;
```

```
                awhi=adt*24*60*60+'11:30't;
```

```
        end;
```

```
        else if avisit in ('Day 90') then do;
```

```
            awlo=adt*24*60*60+'10:00't;
```

```
                awhi=adt*24*60*60+'12:30't;
```

```
        end;
```

```
    end;
```

```
        if avisit in ('Day 5', 'Day 6/Discharge Confinement') and trta in  
('THSm2.2', 'mCC') and nmiss(trtstart)=0 then do;
```

```
            if atptn=0 then do;
```

```
                awlo=trtstart-'00:15't;
```

```
                awhi=trtstart;
```

```
            end;
```

```
            else if atptn=1 then do; /* 2 h */
```

```
                awlo=trtstart+'02:00't;
```

```
    awhi=trtstart+'02:05't;

end;

else if atptn=2 then do; /* 4 h */

    awlo=trtstart+'04:00't;

    awhi=trtstart+'04:05't;

end;

else if atptn=3 then do; /* 6 h */

    awlo=trtstart+'06:00't;

    awhi=trtstart+'06:05't;

end;

else if atptn=4 then do; /* 8 h */

    awlo=trtstart+'08:00't;

    awhi=trtstart+'08:05't;

end;

else if atptn=5 then do; /* 10 h */

    awlo=trtstart+'10:00't;

    awhi=trtstart+'10:05't;

end;

else if atptn=6 then do; /* 12 h */

    awlo=trtstart+'12:00't;

    awhi=trtstart+'12:05't;

end;

else if atptn=7 then do; /* 14 h */

    awlo=trtstart+'14:00't;

    awhi=trtstart+'14:05't;
```

```

end;

else if atptn=8 then do; /* 16 h */

    awlo=trtstart+'16:00't;

    awhi=trtstart+'16:05't;

end;

else if atptn=9 then do; /* 20 h */

    awlo=trtstart+'20:00't;

    awhi=trtstart+'20:05't;

end;

else if atptn=10 then do; /* 24 h */

    awlo=trtstart+'24:00't;

    awhi=trtstart+'24:05't;

end;

```

```

end;

```

```

if trta in ('SA') and nmiss(adl)=0 then do;

    if avisit in ('Day 5') then do;

        awlo=adl*24*60*60+'20:00't;

        awhi=adl*24*60*60+'21:30't;

        end;

        else if avisit in ('Day 6/Discharge Confinement') then do ;

            awlo=adl*24*60*60+'08:00't;

            awhi=adl*24*60*60+'09:30't;

            end;

end;

```

end;

```
if nmiss(awlo, awhi)=0 then awrange=strip(put(awlo,datetime16.)) || '-  
' || strip(put(awhi,datetime16.));
```

run;

data adpc2;

set adpc2;

format devn devw apuper 8. DEVWC apuperc \$10.;

```
if nmiss(PACTIME, PNOMTIME)=0 then DEVN=PACTIME-PNOMTIME;
```

```
if .<ADTM<AWLO then DEVW=(ADTM-AWLO)/60 ;
```

```
else if ADTM>AWHI>. then DEVW=(ADTM-AWHI)/60 ;
```

```
if devw ne . then do;
```

```
devwc = strip(put(round(devw,0.001),best8.3)) || " min";
```

```
if devw gt 0 then devwc = cats("+",devwc);
```

end;

```
if nmiss(DEVN, PNOMTIME)=0 and PNOMTIME ne 0 then  
PCTDEV=ROUND(100*DEVN/PNOMTIME, 0.1);
```

```
if 101<=avisitn<=106 then apuper=1;
```

```
else If 106<avisitn<=131 then apuper=2;
```

```
else if 131<avisitn<=161 then apuper=3;
```

```
else if 161<avisitn<=191 then apuper=4;
```

```

        if apuper=1 then apuperc= 'Period 1';

        else if apuper=2 then apuperc='Period 2';

        else if apuper=3 then apuperc='Period 3';

        else if apuper=4 then apuperc='Period 4';

    if TRTPN=97 | TRTPN=98 then do; APUPER=.; APUPERC = ""; end;

run;

* Analysis records flag;

data adpc2;

    set adpc2;

    format anl01fl $2. aexreas $200.;

        if bloqfl="" and aval ne . then do;

            if avisit in ('Day 0','Day 1','Day 2','Day 3','Day 4', 'Day 5', 'Day 6/Discharge
Confinement' ) then do;

                if nmiss(awlo, awhi, adtm)=0 and awlo <= adtm <= awhi then anl01fl='Y';

                end;

                else if avisit not in ('Day 0','Day 1','Day 2','Day 3','Day 4', 'Day 5',
'Day 6/Discharge Confinement' ) then anl01fl='Y';

                end;

            else if bloqfl='Y' and aval ne . and dtype = "BLQHALF" then anl01fl='Y';

        if compress(fasfl)='N' then aexreas=strip(fasreas);

```

```
if anl01fl="" then aexreas=trim(fasreas);
```

```
run;
```

```
data adpc2;
```

```
set adpc2;
```

```
if not missing(atm) then tm8_dist=abs(atm-'20:00't) ;
```

```
proc sort data=adpc2;
```

```
by usubjid paramn avisit dtype tm8_dist ;
```

```
run ;
```

```
data adpc2;
```

```
set adpc2;
```

```
format anl02fl $2.;
```

```
by usubjid paramn avisit dtype tm8_dist ;
```

```
if first.avisit and aval^=. and upcase(avisit) in ('DAY 0' 'DAY 1' 'DAY 2' 'DAY 3' 'DAY 4' 'DAY 5') then  
anl02fl='Y' ;
```

```
run;
```

```
*change from baseline;
```

```
proc sort data=adpc2;
```

```
by usubjid subjidn paramn avisitn atptn;
```

```
run;
```

```
data base(rename=(aval=base));
```



```

set adpc2 (where=(ablfl='Y'));

keep usubjid subjidn paramn aval;

run;

proc sort data=base ;

    by usubjid subjidn paramn;

run;

* here delete one baseline record from the double baselines in sdtm.pc;

data base;

    set base;

                                by usubjid subjidn paramn;

                                if not first.paramn then delete;

run;

data change;

    merge adpc2 base;

    by usubjid subjidn paramn;

    format chg pchg best. pchgc $20.;

    LENGTH PCREASN2 $200 PCDTC2 $16;

    if nmiss(aval, base)=0 then do;

        chg=aval-base;

        pchg=(aval-base)/base*100;

        pchgc=STRIP(put(round(pchg,0.1),8.1));

    end;

```

```
PCREASN2=PCREASND;
```

```
PCDTC2=PCDTC;
```

```
if subjid='TOK-0146' and ablfl='Y' and aval=33 then ablfl='';
```

```
DROP PCREASND PCDTC;
```

```
RENAME PCREASN2=PCREASND PCDTC2=PCDTC;
```

```
run;
```

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

```
* create output dataset ;
```

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

```
options replace;
```

```
proc sort data = change out=adpc;
```

```
BY USUBJID AVISITN PARAMCD ATPTN;
```

```
run;
```

```
%m_chglength(inds=adpc,varlist=PARAMCD AVALC AVALU PCREASND, lenlist= $3 $11 $5 $41);
```

```
%m_attrib_adam (dset=ADPC);
```

```
data adpc;
```

```
set adpc;
```

```

format _all_;
```

```

format SCRNDT ADT TRTSDT TRTEDT DATE9. AWLO AWHI TRTSDTM TRTEDTM
ADTM DATETIME13. ATM time5.;
```

```

run;
```

```

data adam.adpc (label= 'Pharmacokinetic Concentration Analysis Dataset');
```

```

    set adpc;
```

```

run;
```

```

options noreplace;
```

```

proc printto; run;
```

```

%m_logchk;
```

```

*=====;
```

```

* END OF PROGRAM CODE          ;
```

```

*=====;
```