

/\*-----

Covance Study ID : COV-000000106343

Program Name : d\_2adqspa.sas

Purpose : Program to create ADQSPA dataset

Author : cvn\_pshe

Date of Creation : 31MAR2015

Input Data : ADAM.ADSL, SDTM.QS,

Output Data : ADAM.ADQSPA

Macros Called : m\_printto,%m\_totper, m\_perall, m\_logchk, m\_attrib\_adam

-----  
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 ;
```

```
*=====;
```

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

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

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

```
* bring in ADSL ;
```

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

```
data adsl;
```

```
    set adam.adsl;
```

```
    keep studyid usubjid subjid subjidn siteid age race sex: dthfl height weightbl bmi ucpdgr1  
ucpdgr1n randfl enrfl scrffl exfl exnotrfl enfl complfl fupfl SAFBFL SAFAFL FASFL pprot1fl pprot2fl  
pprot3fl pprot4fl
```

```
    TRTSDTM TRTSTMF TRTSDT TRTSDAY TRTEDTM TRTETMF TRTEDT TRTEDAY trt01p trt01pn trt01a  
trt01an
```

```
;
```

```
run;
```

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

```
* bring in QS ;
```

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

```
data qs1;
```

```
    set sdtm.qs(where = (qscat in ('HUMAN SMOKING TOPOGRAPHY QUESTIONNAIRE')));
```

```
format paramcd $8. parcat1 $200. avisit $40. paramn parcat1n avisitn 8. aval best. param  
$100.
```

```
avalc $50. adt date9. adtm datetime13. atm time5. desc $200.;
```

```
* parameter variables ;
```

```
parcat1 = propcase(qscat);
```

```
parcat1n=2;
```

```
if qstestcd in ('TASTE', 'HSTASTE') then do;
```

```
qstestcd='HSTASTE';
```

```
end;
```

```
paramcd = qstestcd;
```

```
param = propcase(qstest, '.');
```

```
if qstestcd='HSSMOK' then paramn=1;
```

```
else if qstestcd='HSENJ' then paramn=2;
```

```
else if qstestcd='HSTAST' then paramn=3;
```

```
else if qstestcd='HSTASTE' then do; param='Smoking Taste'; paramn=3; end;
```

```
else if qstestcd='HSEASY' then paramn=4;
```

```
else if qstestcd='HSDISTU' then paramn=5;
```

```
else if qstestcd='QSALL' then paramn=99;
```

```
* analysis variables ;
```

```
if qsstresn ^= . then acal =qsstresn;
```

```
else do;
```

```

if scan(qsstresc,1,'-')='STRONGLY DISAGREE' then aval=1;

    else if scan(qsstresc,1,'-')='DISAGREE' then aval=2;

    else if scan(qsstresc,1,'-')='NEITHER AGREE NOR DISAGREE' then aval=3;

    else if scan(qsstresc,1,'-')='AGREE' then aval=4;

    else if scan(qsstresc,1,'-')='STRONGLY AGREE' then aval=5;

        end;

```

```

        avalc = propcase(scan(qsstresc,1,'-'),'/');

        desclen = index(qsstresc,'-');

        if index(qsstresc,'-') then desc = propcase(substr(qsstresc,desclen+1),'.');

desc=tranwrd(desc,'i ','l ');

```

```

        * visit details ;

avisit = propcase(visit);

avisitn = visitnum;

```

```

        * dates;

        if length(qsdtc) gt 10 then do;

ADTM=DHMS(INPUT(SCAN(QSDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(QSDTC,2,'T'),TIME5.)),MINUT
E(INPUT(SCAN(QSDTC,2,'T'),TIME5.)),0);

            adt = datepart(adtm);

            atm = timepart(adtm);

        end;

        else if length(qsdtc) = 10 then adt = input(qsdtc,yyymmdd10.);

```

```
keep usubjid qsseq param: parcat: aval: desc avisit: adt: atm qsstat qsreasnd qsdte qsdyc epoch ;  
run;
```

```
data qs1_base (rename=(aval=base avalc=basec));
```

```
set qs1 (where=(avisit='Day 0'));
```

```
keep usubjid paramn aval avalc;
```

```
run;
```

```
proc sort data=qs1_base;
```

```
by usubjid paramn;
```

```
run;
```

```
proc sort data=qs1;
```

```
by usubjid paramn;
```

```
run;
```

```
data qs1_b;
```

```
merge qs1 qs1_base/*(drop=aval avalc)*/;
```

```
by usubjid paramn;
```

```
format chg pchg best. ablf $2.;
```

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

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

```
chg=.; /*per email from John, set these two variable to null*/
```

```
pchg=.
```

```
/* end; */
```

```
run;
```

```
data qs2;
```

```
set sdtm.qs(where = (qscat in ('MODIFIED CIGARETTE EVALUATION QUESTIONNAIRE')));
```

```
format paramcd $8. parcat1 parcat2 $200. avisit $40. paramn parcat1n parcat2n avisitn aval 8.  
param $100. avalc $50. adt date9.
```

```
adtm datetime13. atm time5. desc $200.;
```

```
* parameter variables ;
```

```
parcat1 = propcase(qscat);
```

```
parcat1n =1;
```

```
if qstestcd in ('DIZZY' 'NAUSEO') then do;
```

```
parcat2 = 'Aversion';
```

```
parcat2n = 1;
```

```
end;
```

```
else if qstestcd = 'CRAVING' then do;
```

```
parcat2 = 'Craving';
```

```
parcat2n = 2;
```

```
end;
```

```
else if qstestcd = 'SENSAT' then do;
```

```
parcat2 = 'Sensations';
```

```
parcat2n = 3;
```

```
end;
```

```
else if qstestcd in ('CALM' 'AWAKE' 'IRRITAB' 'CONCEN' 'HUNGER') then do;
```

```
parcat2 = 'Psychological';
```

```

        parcat2n = 4;
end;
else if qstestcd in ('SATISFY' 'TASTE' 'ENJOY') then do;
    parcat2 = 'Satisfaction';
    parcat2n = 5;
end;

paramcd = qstestcd;

    param = propcase(qstest, '.');

if qstestcd = 'SATISFY' then paramn = 6;

    else if qstestcd = 'TASTE' then paramn = 7;
    else if qstestcd = 'SENSAT' then paramn = 8;
    else if qstestcd = 'CALM' then paramn = 9;
    else if qstestcd = 'AWAKE' then paramn = 10;
    else if qstestcd = 'IRRITAB' then paramn = 11;
    else if qstestcd = 'CONCEN' then paramn = 12;
    else if qstestcd = 'HUNGER' then paramn = 13;
    else if qstestcd = 'DIZZY' then paramn = 14;
    else if qstestcd = 'NAUSEO' then paramn = 15;
    else if qstestcd = 'CRAVING' then paramn = 16;
    else if qstestcd = 'ENJOY' then paramn = 17;

        else if qstestcd='QSALL' then paramn=99;

    else put 'USER WARN' 'ING: check parameter names as paramn not allocated:' qstestcd = ;

```

\* analysis variables ;

```
if qsstresc='NOT AT ALL' then aval=1;

else if qsstresc='VERY LITTLE' then aval=2;

else if qsstresc='LITTLE' then aval=3;

else if qsstresc='MODERATELY' then aval=4;

else if qsstresc='A LOT' then aval=5;

else if qsstresc='QUITE A LOT' then aval=6;

else if qsstresc='EXTREMELY' then aval=7;
```

```
avalc = propcase(scan(qsstresc,1,'-'),'');
```

```
descclen = index(qsstresc,'-');
```

```
if index(qsstresc,'-') then desc = propcase(substr(qsstresc,descclen+1),'.');
```

```
desc=tranwrd(desc,'i ','I');
```

\* visit details ;

```
avisit = propcase(visit);
```

```
avisitn = visitnum;
```

\* dates;

```
if length(qsdtc) gt 10 then do;
```

```
ADTM=DHMS(INPUT(SCAN(QSDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(QSDTC,2,'T'),TIME5.)),MINUT  
E(INPUT(SCAN(QSDTC,2,'T'),TIME5.)),0); /* 19) KB 01Jul2014 */
```

```
adt = datepart(adtm);
```

```
atm = timepart(adtm);
```

```
end;
```



```
else if length(qsdtc) = 10 then adt = input(qsdtc, yymmdd10.);
```

```
keep usubjid qsseq param: parcat: aval: desc avisit: adt: atm qsstat qsreasnd qsdtc qsdyc epoch;  
run;
```

```
data qs2_base;  
    set qs2 (where=(avisit in ('Day -1' 'Day 0' 'Day 1')));  
run;
```

```
proc sort data=qs2_base;  
    by usubjid parcat1n parcat2n avisitn qsdtc qsdyc atm;  
run;
```

```
data qs2_base;  
    set qs2_base;  
  
        by usubjid parcat1n parcat2n avisitn adtm;  
        retain adtmb;  
        if last.parcat2n then do;  
            adtmb=.;  
        end;  
  
    if avisit='Day 1' then do;  
        if adtm < dhms(adtm,10,00, 0) then adtmb=adtm;  
        else adtmb=.;  
    end;
```

```

                else do;
if avisit='Day 0' then adtmb=adtm;

                else if avisit='Day -1' then adtmb=adtm;

                end;

                if adtmb =. then delete;

run;

proc sort data=qs2;

    by usubjid parcat1n parcat2n avisitn;

run;

data qs2_base;

set qs2_base;

                by usubjid parcat1n parcat2n avisitn adtmb;

                if last.parcat2n;

run;

data qs2_b;

    merge qs2 qs2_base(drop=QSSEQ QSSTAT QSREASND EPOCH DESC paramcd parcat1 avisit paramn
aval param avalc adt adtm parcat2 qsdtc qsdyc atm in=inbase);

    by usubjid parcat1n parcat2n avisitn;

    if inbase then do;

        ablfl = 'Y';

    end;

run;

proc sort data=qs2_b;

```

```

    by usubjid parcat1n parcat2n param avisitn atm;

run;

data qs2_b;

    set qs2_b;

        by usubjid parcat1n parcat2n param avisitn atm;

        format basec $50.;

        retain base basec;

        if first.param then do; base=.; basec=""; end;

        if ablfl = 'Y' then do; base=aval; basec=avalc; end;

run;

data qs2_b;

    set qs2_b;

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

            chg=aval-base;

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

            end;

run;

* derive subscale scores ;

proc sort data = qs2_b;

    by usubjid parcat1n parcat2n avisitn qsdtc qsdyc adtm adt atm;

run;

```

```

data qs2_1;

  set qs2_b;

      where paramcd ne "QSALL";

          run;

proc summary data = qs2_1 (where = (upcase(parcat1) = 'MODIFIED CIGARETTE EVALUATION
QUESTIONNAIRE')) noprint;

  var aval;

  by usubjid parcat1n parcat1 parcat2n parcat2 avisitn avisit qsdte qsdyc adtm adt atm;

  output out = mean(drop = _)  mean = mean n = n nmiss = nmiss;

run;

data mean2(drop = mean n nmiss);

  set mean;

      format paramcd $8. paramn 8. param $100. paramtyp dtype $10. aval best. avalc $50.;

      paramtyp = 'DERIVED';

      dtype = 'AVERAGE';

      if not missing (mean) then aval = round(mean,0.1);

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

      if parcat2n = 1 then do;

          paramcd = 'MCEQA';

          paramn = 18;

```

```

        param = 'Aversion Subscale';
    end;
else if parcat2n = 2 then do;
        paramcd = 'MCEQCR';
        paramn = 19;
        param = 'Craving Reduction Subscale';
    end;
else if parcat2n = 3 then do;
        paramcd      = 'MCEQERTS';
        paramn = 20;
        param = 'Enjoyment of Respiratory Tract Sensation Subscale';
    end;

    if nmiss = 0 or (nmiss > 0 and (n/nmiss)*100 > 50) then
do;

        if parcat2n = 4 then do;
            paramcd = 'MCEQPR';
            paramn = 21;
            param = 'Psychological Reward Subscale';
        end;
    else if parcat2n = 5 then do;
        paramcd = 'MCEQSS';
        paramn = 22;
        param = 'Smoking Satisfaction Subscale';
    end;
end;

```

```

end;

    else do;

        aval = .;                * > 50% missing;

        avalc = ' ';

    end;

run;

**Baseline for the derived **;

PROC sort data = mean2(where=(avisit in ('Day -1' 'Day 0' 'Day 1'))) out=meanbase;

    by usubjid parcat1n parcat2n avisitn qsdtc qsdym atmm;

run;

data meanbase;

    set meanbase;

        by usubjid parcat1n parcat2n avisitn adtm;

        retain adtmb;

        if last.parcat2n then do;

            adtmb=.;

        end;

    if avisit='Day 1' then do;

        if adtm < dhms(adtm,10,00, 0) then adtmb=adtm;

        else adtmb=.;

    end;

    else do;

        if avisit='Day 0' then adtmb=adtm;

```

```

        else if avisit='Day -1' then adtmb=adtm;

        end;

        if adtmb =. then delete;

run;

data meanbase;

set meanbase;

        by usubjid parcat1n parcat2n avisitn adtmb;

        if last.parc2n;

run;

data meanbase;

merge mean2 meanbase(drop=paramcd parcat1 avisit paramn aval param avalc adt adtm parcat2
paramtyp dtype qsdtc qsdty atm in=inbase);

by usubjid parcat1n parcat2n avisitn;

if inbase then do;

    ablfl = 'Y';

end;

run;

proc sort data=meanbase;

by usubjid parcat1n parcat2n param avisitn atm;

run;

data meanbase;

set meanbase;

```

```
by usubjid parcat1n parcat2n param avisitn atm;  
  
format basec $50.;  
  
retain base basec;  
  
if first.param then do; base=.; basec=""; end;  
  
if ablfl = 'Y' then do; base=aval; basec=avalc; end;
```

```
run;
```

```
data meanbase;
```

```
set meanbase;
```

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

```
chg=aval-base;
```

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

```
end;
```

```
run;
```

```
* set together ;
```

```
data qs;
```

```
set qs1_b qs2_b meanbase;
```

```
format asper apuper 8. asperc $40. apuper $10. ;
```

```
if avisitn < 101 then asper=1;
```

```
else if 101<=avisitn<=106 then asper=2;
```

```
else if 106<avisitn<=191 then asper=3;
```

```
else if avisitn>191 then asper=4;
```



```

        if asper=1 then asperc= 'Pre-Randomization Period';

        else if asper=2 then asperc='Confinement Period';

        else if asper=3 then asperc='Ambulatory Period';

        else if asper=4 then asperc='Safety Follow-up Period';

    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';

run;

proc sort data=qs;

    by usubjid;

run;

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

```

```

* treatment period;

%m_totper;

data slqspa (drop=trt01p trt01pn trt01a trt01an);

    format aperiod trtan trtpn aday 8. trta trtp $40. aperiodc $10.;

    merge adsl qs(in=qs);

    by usubjid;

    if qs;

if randfl ='N' then do;

ablfl = "";

                base=.;

                chg=.;

                pchg=.;

                basec="";

                end;

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

    * allocate tretament and period;

    %m_perall(dvar1 = adtm, dvar2 = adt);

if not missing(aperiod) then do;

    aperiodc = 'Period ' || put(aperiod,1.);

end;

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

run;

```

```
proc sort data=slqspa;  
    by usubjid paramcd avisitn ;  
run;
```

```
data slqspa2;  
    set slqspa;  
    by usubjid paramcd avisitn ;  
    format awlo awhi time5. awrange $50. anl01fl $2.;
```

```
        if randfl='Y' and aval ^=. and first.avisitn then do;  
            if parcat1n=2 then anl01fl='Y';  
            else if parcat1n=1 and paramtyp ='DERIVED' then anl01fl='Y';  
        end;
```

```
if parcat1 ne 'Human Smoking Topography Questionnaire' then do;  
    awlo=dhms(0,20,0,0);  
    awhi=dhms(0,23,0,0);  
end;
```

```
        if parcat1='Human Smoking Topography Questionnaire' then do;  
            if avisit in ('Day 0') then do;  
                awlo=dhms (0,20,0,0);  
                awhi=dhms(0,23,0,0);  
            end;  
            else if trta in ('THSm2.2' 'mCC') and avisit in ('Day 4', 'Day 30', 'Day 60', 'Day 90' ) then do;
```

```

awlo=dhms (0,20,0,0);

awhi=dhms(0,21,30,0);

end;

end;

if nmiss (awlo, awhi) =0 then awrange=strip(put(awlo,time5. ))||'-'||strip(put(awhi,time5.));

run;

DATA Slqspa2;

SET slqspa2;

FORMAT DEVWC $10. DEVN BEST.;

IF QSSTAT NE 'NOT DONE' AND TRTA NE 'SA' THEN DO;

    IF ATM<AWLO and nmiss(atm, awlo)=0 THEN DO;

        DEVN=FLOOR((ATM-AWLO)/60);

        DEVWC=COMPRESS(PUT(FLOOR((ATM-AWLO)/60),BEST.));

    END;

    ELSE IF ATM>AWHI and nmiss(atm, awlo)=0 THEN DO;

        DEVN=CEIL((ATM-AWHI)/60);

        DEVWC=COMPRESS(PUT(CEIL((ATM-AWHI)/60),BEST.));

    END;

END;

IF NOT MISSING(DEVWC) THEN DO;

    IF INDEX(DEVWC,'-')=0 THEN DEVWC=CATS(CATS('+',DEVWC),' min');

```

```

        ELSE IF INDEX(DEVWC,'-') THEN DEVWC=CATS(DEVWC,' min');

    END;

RUN;

*****.

* create output dataset ;

*****.

options replace;

proc sort data = Slqspa2 out=adqspa;

    by usubjid avisitn parcat1 paramcd;

run;

%m_attrib_adam (dset=ADQSPA);

data adam.adqspa (label= 'Product Assessment Analysis Dataset');

    set adqspa;

run;

options noreplace;

proc printto; run;

```

%m\_logchk;

\*=====;

\* END OF PROGRAM CODE ;

\*=====;