

/*=====

Covance Study ID : COV-000000106331

Program Name : d_adsl.sas

Purpose : Program to ADSL dataset

Author : siva karnati

Date of Creation : 9MAR2015

Input Data : SDTM.DM,SDTM.DS,SDTM.DV,SDTM.DX

SDTM.EX,SDTM.FA,SDTM.LB,SDTM.SU,

SDTM.SV,SDTM.VS

Output Data :

Macros Called :

=====

Modification History

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Modified by :

Modification Date :

Modification Description :

=====*/

OPTIONS VALIDVARNAME=UPCASE missing=" " replace;

PROC DATASETS LIBRARY=WORK KILL NOLIST;

RUN;

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

```
libname sdtm "/cvn/projects/prj/data/000000106331/datasets/sdtm/sdtmx";
```

```
%m_printto(route=YES);
```

```
proc format;
```

```
value pucat
```

```
0-4.99="Primarily CC"
```

```
5-29.99="Predominantly CC"
```

```
30-39.99="Dual Mostly CC"
```

```
40-59.99="Dual Balanced"
```

```
60-69.99="Dual Mostly THS 2.2"
```

```
70-94.99="Predominantly THS 2.2"
```

```
95-100="Primarily THS 2.2"
```

```
;
```

```
value $mccpucatn
```

```
"CC Only"=1
```

```
"CC Dual"=2
```

```
"Primarily THS 2.2"=3
```

```
"Predominantly THS 2.2"=4
```

```
"Dual Mostly THS 2.2"=5
```

```
"Dual Balanced" =6
```

```
"Dual Mostly CC"=7
```

```
"Predominantly CC"=8
```

```
"Primarily CC"=9
```

```
"Not Abstinent" =10
```

```
"Predominantly Abstinent"=11
```

```
'Abstinent' =12
```

```
'Missing'=99;
```

```
;
```

```
value gpucat
```

```
0-29.99="CC"
```

```
30-69.99="Dual"
```

```
70-100="THS 2.2";
```

```
value $ccgpucat
```

```
"CC"=1
```

```
"THS 2.2"=2
```

```
"Dual"=3
```

```
"Not Abstinent" =4
```

```
"Predominantly Abstinent"=5
```

```
'Abstinent' =6
```

```
'Missing'=99;
```

```
run;
```

```
data dm;
```

```
set sdtm.dm;
```

```
length subjidn sexn racen 8. sexc $20.;
```

```
format brthdt date9.;
```

```
subjdn=input(scan(subjid,2,"-"),??best.);
```

```
brthdt=input(brthdtc,yyymmdd10.);
```

```
if sex = 'M' then
```

```
    do;
```

```
        /*sex sexn*/
```

```
        sexc = 'Male';
```

```
        sexn = 1;
```

```
    end;
```

```
else if sex = 'F' then
```

```
    do;
```

```
        sexc = 'Female';
```

```
        sexn = 2;
```

```
    end;
```

```
/*race racen*/
```

```
if race='WHITE' then
```

```
    racen=1;
```

```
else if race='BLACK OR AFRICAN AMERICAN' then
```

```
    racen=2;
```

```
else if race='AMERICAN INDIAN OR ALASKA NATIVE' then
```

```
    racen=3;
```

```
else if race='ASIAN' then
```

```
    racen=4;
```

```
else if race='NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER' then
```

```
        racen=5;
else if race='OTHER' then
        racen=6;

if ethnic='CAUCASIAN' then
        ethnictn=1;
else if ethnic='NOT CAUCASIAN' then
        ethnictn=2;
else if ethnic = 'JAPANESE' then
        ethnictn = 3;
else if ethnic = 'NOT JAPANESE' then
        ethnictn = 4;
else if ethnic = 'HISPANIC OR LATINO' then
        ethnictn=5;
else if ethnic = 'NOT HISPANIC OR LATINO' then
        ethnictn=6;

if armcd = 'THS 2.2M' then
        armcdn = 5;
else if armcd = 'MCC' then
        armcdn = 6;
else if armcd = 'SMABST' then
        armcdn = 3;
else if armcd = 'SCRNFAIL' then
        armcdn = 4;
```

```

ELSE IF ARMCD='NOTASSGN' THEN

    ARMCDN=20;

ELSE PUT "USER WA" "RNING: Check ARMCDs " ARMCD=;

keep studyid usubjid subjid subjidn siteid age ageu brthdtc brthdt sex sexc sexn race racen
ethnic: country arm

    armcd dthfl armcdn rfstdtc;

run;

proc sort data=sdtm.suppdm out=suppdm; by usubjid; run;

proc transpose data=suppdm out=suppdm_(drop=_name__label_);
by usubjid;
var qval;
id qnam;
run;

proc sort data=dm;
by usubjid;
run;

data dm1;

merge dm(in=a) suppdm_(in=b rename=(dmrandno=dmrandno_/*raceoth=raceoth_*/));

by usubjid;

length dmrandno $10. ;

dmrandno=strip(dmrandno_);

drop dmrandno_;

```

```
run;
```

```
/* VS data*/
```

```
data height;
```

```
    set sdtm.vs(where=(vstestcd in("HEIGHT")));
```

```
    if vstestcd="HEIGHT" and vsblfl ne "Y" then
```

```
        delete;
```

```
    keep usubjid vsstresn;
```

```
    rename vsstresn=height;
```

```
run;
```

```
/* to get the latest value of weight from VS*/
```

```
proc sort data=sdtm.vs(where=(vstestcd eq "WEIGHT" and visit="DAY -2")) out=weight1a(keep=usubjid  
vsstresn rename=(vsstresn=weightbl));
```

```
    by usubjid vsdtc;
```

```
run;
```

```
proc sort data=height;
```

```
    by usubjid;
```

```
run;
```

```
data vs;
```

```
    merge height weight1a;
```

```
    by usubjid;
```

```
    format BMI 8.1;
```

```

length bmigr1 $40. bmigr1n 8.;

if nmiss(WEIGHTBL,HEIGHT)=0 then bmi=round((WEIGHTBL/((HEIGHT/100)**2)),0.1);

if 0 < bmi < 18.5 then

    do;

        bmigr1 = 'Underweight';

        bmigr1n = 1;

    end;

else if 18.5 <= bmi < 25 then

    do;

        bmigr1 = 'Normal weight';

        bmigr1n = 2;

    end;

else if 25 <= bmi < 30 then

    do;

        bmigr1 = 'Overweight';

        bmigr1n = 3;

    end;

else if bmi >= 30 then

    do;

        bmigr1 = 'Obese';

        bmigr1n = 4;

    end;

run;

*****
,

```



```

* add to DM;

*****;

data dm2;

    merge DM1(in = a) vs(in = b);

    by usubjid;

run;

*****;

* Bring in daily cigarette consumption for classification in summary and analysis;

* This may originate by questionnaire or from randomisation;

* Check study aCRF and specifications for more information;

*****;

data fa(keep = usubjid ucpdgr:);

    set sdtm.fa(where=(faobj = 'SMOKING HISTORY' and fatestd = 'SMOKHIST' and
epoch='SCREENING'));

    length ucpdgr1 $40. ucpdgr1n 8.;

    if index(FAORRES,'<10') then    do;

        ucpdgr1n = 1;

        ucpdgr1 = '<10 cig/day';

    end;

    else if FAORRES = '10 TO 19' then do;

        ucpdgr1n = 2;

        ucpdgr1 = '10-19 cig/day';

    end;

    else if index(FAORRES,'>19') then

```

```

do;

    ucpdgr1n = 3;

    ucpdgr1 = '>19 cig/day';

end;

/*      else put 'USER WARN' 'ING unable to classify daily cigarette consumption: ' usubjid=
/*fastresc*/ */

FAORRES=;

output;

* only keep usual daily cig consumption;

run;

data dm3;

    merge dm2(in = a) fa(in = b);

    by usubjid;

run;

*****;

* Bring in baseline cig nicotine yield for classification in summary and analysis;

* for baseline only - check specifications;

* Check study aCRF and specifications for more information;

*****;

data fa1(keep = usubjid nico: fatestd epoch);

    set sdtm.fa(where = ((fatestcd='NYIELD') and epoch = 'ADMI'));

    length nicobl 8. nicogr1n 8. nicogr1 $20.;

    nicobl = fastresn;

```

```

if not missing(nicobl) and nicobl le 0.6 then
    do;
        nicogr1 = '<= 0.6 mg';
        nicogr1n = 1;
    end;
else if nicobl > 0.6 then
    do;
        nicogr1 = '> 0.6 mg';
        nicogr1n = 2;
    end;
output;
run;

*****;

* Bring in baseline tar yield for classification in summary and analysis;

* for baseline only - check specifications;

* Check study aCRF and specifications for more information;

*****;

data fa2(keep = usubjid tar:);

    set sdtm.fa(where = (fatestcd = 'TYIELD' and epoch = 'ADMI'));

    length tarbl targr1n 8. targr1 $20.;

    tarbl = fastresn;

    if 1 le FLOOR(tarbl) le 5 then

```

```

do;

    /* 14) KB 29Jun2014 */

    targr1 = '1-5 mg';

    targr1n = 1;

end;

else if 6 le FLOOR(tarbl) le 8 then

do;

    /* 14) KB 29Jun2014 */

    targr1 = '6-8 mg';

    targr1n = 2;

end;

else if 9 le FLOOR(tarbl) le 10 then

do;

    /* 14) KB 29Jun2014 */

    targr1 = '9-10 mg';

    targr1n = 3;

end;

else if tarbl gt 10 then

do;

    targr1 = '>10 mg';

    targr1n = 4;

end;

output;

* only keep tar yield information;

```

```
run;
```

```
/* Bring in baseline CO level data */
```

```
data co(keep=usubjid cobl);
```

```
    set sdtm.su(where=(sutrt='CONVENTIONAL CIGARETTES' and epoch='BASELINE'));
```

```
    attrib cobl length=$20.;
```

```
    cobl=strip(sudostxt);
```

```
run;
```

```
data dm4;
```

```
    merge dm3(in = a) fa1(in = b) fa2(in = c) co(in=d);
```

```
    by usubjid;
```

```
run;
```

```
data perf;
```

```
    set sdtm.fa;
```

```
    where fatestd = "PERFORM" and faorres="Y";
```

```
    keep usubjid;
```

```
run;
```

```
proc sort data = sdtm.ie out = ie(keep = usubjid) nodupkey;
```

```
    by usubjid;
```

```
run;
```

```
data dm5;
```

```

merge dm4(in=a) ie(in=b) perf(in=c);

by usubjid;

length ENRLFL SCRFFL RANDFL enfl $2.;

if (b or not c) and dmrando eq "" then
    enrfl="N";
else enrfl="Y";

if enrfl="Y" then
    scrffl="N";
else if enrfl="N" then
    scrffl="Y";

if dmrando ne "" then
    randfl="Y";
else randfl="N";

If ENRLFL="Y" and RANDFL="N" then
    ENFL='Y';
else ENFL='N';

run;

/* to populate BMI and weight for product test arm subjects*/

data dm5_1;

set dm5;

```

```

where enfl="Y";

keep  usubjid enfl;

run;

proc sort data=sdtm.vs out=vs_pt_wt(keep=usubjid vsstresn rename=(vsstresn=weight_pt));

by usubjid;

where vstestcd in ("WEIGHT");

RUN;

data  wt_pt;

merge dm5_1(in=a) vs_pt_Wt(in=b);

if a  and b;

by usubjid;

run;


proc sort data=wt_pt;by usubjid; run;

data  wt_pt1;

set wt_pt;

by usubjid;

if last.usubjid;

run;

proc sort data=sdtm.vs out=vs_pt_ht(keep=usubjid vsstresn rename=(vsstresn=height_pt));

by usubjid;

where vstestcd in ("HEIGHT");

RUN;

data  ht_pt;

merge dm5_1(in=a) vs_pt_ht(in=b);

```

```

if a and b;

by usubjid;

run;


proc sort data=ht_pt;by usubjid; run;

data ht_pt1;

set ht_pt;

by usubjid;

if last.usubjid;

run;

data bmi_pt;

merge ht_pt1(in=a drop=enfl) wt_pt1(in=b);

by usubjid;

format BMI_pt 8.1;

length bmigr1_pt $40. bmigr1n_pt 8.;

bmi_pt=round((WEIGHT_pt/((HEIGHT_pt/100)**2)),0.1);


if 0 < bmi_pt < 18.5 then

do;

bmigr1_pt = 'Underweight';

bmigr1n_pt = 1;

end;

else if 18.5 <= bmi_pt < 25 then

do;

bmigr1_pt = 'Normal weight';

```



```

        bmigr1n_pt = 2;
    end;
else if 25 <= bmi_pt < 30 then
    do;
        bmigr1_pt = 'Overweight';
        bmigr1n_pt = 3;
    end;
else if bmi_pt >= 30 then
    do;
        bmigr1_pt = 'Obese';
        bmigr1n_pt = 4;
    end;

run;

data dm5;
merge dm5(in=a) bmi_pt(drop=enfl);
by usubjid;
if enfl="Y" then do;
height=HEIGHT_pt;
weightbl=WEIGHT_pt;
bmi=bmi_pt ;
bmigr1=bmigr1_pt;
bmigr1n=bmigr1n_pt;
end;

```

```
run;
```

```
/* Obtain device test data */
```

```
proc sort data = sdtm.dx out = dx(where = (not missing(dxstdtc) /*and epoch="ADMI" */) nodupkey;
```

```
    by usubjid /*dxstdtc*/;
```

```
run;
```

```
proc sort data = sdtm.dx (where = (not missing(dxstdtc) and epoch="ADMI" ))out =  
dx_1(rename=(dxstdtc=dxstdtc_) keep=usubjid dxstdtc) nodupkey;
```

```
    by usubjid dxstdtc;
```

```
run;
```

```
data dx_1;
```

```
set dx_1;
```

```
by usubjid dxstdtc_;
```

```
if first.usubjid;
```

```
run;
```

```
data dm6;
```

```
merge dm5(in=a) dx(in=b keep=usubjid dxstdtc ) dx_1(in=c );
```

```
by usubjid;
```

```
if first.usubjid;
```

```
format exfl exnotrfl $2.;
```

```
if (a and b) and enrfl="N" then
```

```
    exfl="Y";
```

```
else exfl="N";
```

```

if (a and b )and randfl="N" then
    exnotrfl="Y";
else exnotrfl="N";
format dtestdtm datetime13. dtestdt date9. dtesttm time5.;

if length(dxstdtc_) gt 10 then

    DTESTDTM=DHMS(INPUT(SCAN(DXSTDTC_,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(DXSTDTC_,2,'
T'),TIME5.)),MINUTE(INPUT(SCAN(DXSTDTC_,2,'T'),TIME5.)),0);

    else if length(dxstdtc_)=10 then

        dtestdtm=dhms(input(dxstdtc_,yymmdd10.),0,0,0);

if dtestdtm ne . then

    dtesttm= timepart(dtestdtm);

if dtestdtm ne . then

    dtestdt = datepart(dtestdtm);

run;

*****.

* bring in exposure data;

*****.

* SA data;

proc sort data = sdtm.sv(where = (visitdy=1)) out=sa;

```

```

        by usubjid svstdtc;

run;

data saarm(keep = usubjid exstdtc_ );

    merge sa sdtm.dm(keep = usubjid armcd);

    by usubjid;

    format exstdtc_ $16.;

    exstdtc_ = trim(svstdtc) || 'T10:00';


    if armcd = 'SMABST' then output;          * only keep SA arm subjects;

run;


* device admin data;

data dx;

    set sdtm.dx(where = (not missing(dxstdtc) and dxstdy ge 1)); * don't include device test data;

    LENGTH EXSTDTC EXENDTC $16 EXCAT $60;

    EXSTDTC=DXSTDTC;

    EXENDTC=DXENDTC;

    EXSTDY=DXSTDY;

    EXCAT=DXCAT;

    keep usubjid exstdtc exendtc exstdy excat visit epoch;

run;


proc sort data = dx;

    by usubjid exstdtc;

```

```
run;
```

```
data dx1;
```

```
    set dx;
```

```
    by usubjid exstdtc;
```

```
    if first.usubjid;
```

```
    keep usubjid exstdtc ;
```

```
run;
```

```
* cc admin data;
```

```
data ex;
```

```
    set sdtm.ex(where=(exstdy ge 1 and not missing(exstdtc)));
```

```
run;
```

```
proc sort data=ex(where=(epoch='PRODUCT USE CONFINEMENT')) out=ex_epoch(keep=usubjid epoch)  
nodupkey;
```

```
by usubjid; run;
```

```
proc sort data=dx(where=(epoch='PRODUCT USE CONFINEMENT')) out=dx_epoch(keep=usubjid epoch)  
nodupkey;
```

```
by usubjid; run;
```

```
data exdx_epoch;
```

```
set ex_epoch dx_epoch;
```

```
by usubjid;
```

```
run;
```

```
proc sort data=exdx_epoch nodupkey;by usubjid; run;
```

```
proc sort data = ex out=ex1(where=(exstdy=1));
```

```
    by usubjid;
```

```
run;
```

```
* combine for full product admin set;
```

```
data exp;
```

```
    set dx    ex1;
```

```
    by usubjid;
```

```
    keep usubjid exstdtc exendtc exstdy excat visit epoch;
```

```
run;
```

```
proc sort data=exp /*(where=(exstdy=1))*/ out=exp_st;
```

```
    by usubjid exstdtc ;
```

```
run;
```

```
data exp_st1;
```

```
    set exp_st;
```

```
    by usubjid;
```

```
    if first.usubjid;
```

```
run;
```

```
* combine with SA;
```

```
data exp_st2;
```

```
    merge exp_st1(in=exdx) saarm(in=none );
```

```
    by usubjid;
```

```
    if none then do;
```

```
        excat='SMOKING ABSTINENCE';
```

```

exstdtc=exstdtc_;

end;

drop exstdtc_;

run;

/* TRTSDTM TRTSTMF TRTSDT */

data ex_start1;

    set exp_st2;

    format trtsdtm datetime13. trtsdt date9.;

    length trtstmf $1.;

    if length (exstdtc)>10 then

        TRTSDTM=DHMS(INPUT(SCAN(EXSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(EXSTDTC,2,'T'),TIME5.)),MINUTE(INPUT(SCAN(EXSTDTC,2,'T'),TIME5.)),0);

        else if length(exstdtc)=10 then trtsdtm=dhms(input(exstdtc,yyymmdd10.),0,0,0);

        trtsdt = datepart(trtsdtm);

        if excat ="SMOKING ABSTINENCE" then do;

            trtstmf="H";

        end;

    keep usubjid trtsdtm trtsdt trtstmf ;

run;

proc sort data=ex_start1;by usubjid;run;

data ex_start;

```

```
merge ex_start1(in=a) exdx_epoch(keep=usubjid epoch);
```

```
by usubjid;
```

```
if a;
```

```
    rename epoch=epoch_exdx;
```

```
run;
```

```
/* To find exendtc*/
```

```
proc sort data=dx out=dx_en;
```

```
    by usubjid exendtc;
```

```
    where visit eq "DAY 90";
```

```
run;
```

```
data dx_en90;
```

```
set dx_en;
```

```
by usubjid exendtc;
```

```
if last.usubjid;
```

```
keep usubjid exendtc;
```

```
rename exendtc=exendtc_d90;
```

```
run;
```

```
data dx1;
```

```
    set sdtm.dx(where = (not missing(dxstdtc) and dxstdy>=1 and dxdose>0) ); * don't include  
device test data;
```

```
    LENGTH EXENDTC $16 EXCAT $60;
```

```
    EXSTDTC=DXSTDTC;
```

```
    EXENDTC=DXENDTC;
```

```
    EXSTDY=DXSTDY;
```

```
    EXCAT=DXCAT;
```



```
run;
```

```
proc sort data=sdtm.dm(keep = usubjid armcd) out=dm_a; by usubjid; run;
```

```
proc sort data=dx1 out=dx_en2a;
```

```
by usubjid exendtc;
```

```
run;
```

```
data dx_en2;
```

```
merge dx_en2a(in=a) dm_a(in=b); /* to get the maximum date from the corresponding arm*/
```

```
by usubjid;
```

```
if armcd="THS 2.2M";
```

```
run;
```

```
data dx_dnon;
```

```
set dx_en2;
```

```
by usubjid exendtc;
```

```
if last.usubjid;
```

```
keep usubjid exendtc;
```

```
rename exendtc=exendtc_dnon;
```

```
run;
```

```
data ex_e;
```

```
set sdtm.ex(where=( not missing(exendtc) and exstdy>=1 and exdose>0));/*exdose>0 is added  
as per the feedback from John*/
```

```
run;
```

```
proc sort data=ex_e out=ex_en;
```

```
by usubjid exendtc;
```

```
        where visit eq "DAY 90";

run;

data ex_en90;

    set ex_en;

    by usubjid exendtc;

    if last.usubjid;

    keep usubjid exendtc;

    rename exendtc=exendtc_d90;

run;

proc sort data=ex_e out=ex_en2a;

    by usubjid exendtc;

run;
```

```
data ex_en2;

    merge ex_en2a(in=a) dm_a(in=b);    /* to get the maximum date from the corresponding arm*/

    by usubjid;

    if armcd="MCC";

run;

data ex_dnon;

    set ex_en2;

    by usubjid exendtc;

    if last.usubjid;

    keep usubjid exendtc;

    rename exendtc=exendtc_dnon;
```

```
run;
```

```
data exen_d90;
```

```
set ex_en90 dx_en90;
```

```
run;
```

```
proc sort data=exen_d90;by usubjid exendtc_d90; run;
```

```
data exen_d90a;
```

```
set exen_d90;
```

```
by usubjid exendtc_d90;
```

```
if last.usubjid;
```

```
run;
```

```
data exend_dnon;
```

```
set ex_dnon dx_dnon;;
```

```
run;
```

```
proc sort data=exend_dnon;by usubjid exendtc_dnon; run;
```

```
data exend_dnon1;
```

```
set exend_dnon;
```

```
by usubjid exendtc_dnon;
```

```
if last.usubjid;
```

```
run;
```

```
data ds1;
```

```
set sdtm.ds;
```

```
run;
```

```
data suppds;
```

```
    set sdtm.suppds;
```

```
    dsseq=input(idvarval,??best.);
```

```
    where qnam="OTHER";
```

```
    keep usubjid dsseq qval;
```

```
run;
```

```
proc sort data=ds1;
```

```
    by usubjid dsseq;
```

```
run;
```

```
proc sort data=suppds;
```

```
    by usubjid dsseq;
```

```
run;
```

```
data ds;
```

```
    merge ds1(in=a) suppds;
```

```
    by usubjid dsseq;
```

```
    format dsreasp $200.;
```

```
    dsreasp=strip(qval);
```

```
run;
```

```
proc sort data=ds(where=(dsdecod="COMPLETED")) out=comp(keep=usubjid);
```

```
by usubjid;
```

```

run;

/*data ex_end;*/

/*merge exen_d90a exend_dnon1 comp(in=a);*/

/*by usubjid;*/

/*if a then flag=1;*/

/*if /*flag^=1 and /*/*exendtc_d90 eq "" then exendtc_d90=exendtc_dnon;*/

/*keep usubjid exendtc_d90;*/

/*run;*/

```

```

data ex_end1a;

set exen_d90a exend_dnon1(rename=(EXENDTC_DNON=EXENDTC_D90)) ;

run;

```

```

proc sort data=ex_end1a;by usubjid exendtc_d90;run;

```

```

data ex_end;

set ex_end1a;

by usubjid exendtc_d90;

if last.usubjid;

run;

proc sort data = sdtm.sv out=sa_end;

    by usubjid svendtc;

    where visit ne "DAY 6/DISCHARGE CONFINEMENT";

run;

```

```

data saarm_end(keep = usubjid exendtc_ );

    merge sa_end sdtm.dm(keep = usubjid armcd);

    by usubjid;

    if last.usubjid;

    format exendtc_ $16.;

    exendtc_ = trim(svendtc) || 'T23:00';


    if armcd = 'SMABST' then output;      * only keep SA arm subjects;

run;

```

* combine with SA;

```

data exp_end3;

    merge ex_end(in=exdx) saarm_end(in=none ) ;

    by usubjid;


    if none then do;

        excat='SMOKING ABSTINENCE';

        exendtc=exendtc_;

    end;


    if exendtc eq "" then

        exendtc=EXENDTC_d90;

    drop exendtc_;

run;

```

```

data ex_end;

    set exp_end3;

    format trtedtm datetime13. trtedt date9.;

    length trtetmf $1.;

    if not missing(exendtc) then do;

        if length(exendtc)>10 then do;

            TRTEDTM=DHMS(INPUT(SCAN(exendtc,1,'T'),YYMMDD10.),
            HOUR(INPUT(SCAN(exendtc,2,'T'),TIME5.)),
            MINUTE(INPUT(SCAN(exendtc,2,'T'),TIME5.)),0);

            end;

        else if length(exendtc)=10 then do;

            trtedtm=dhms(INPUT(exendtc,YYMMDD10.),23,0,0);

            trtetmf="H";

        end;

        trtedt = datepart(trtedtm);

        if excat ="SMOKING ABSTINENCE" then

            do;

                trtetmf="H";

            end;

        end;

    end;

    keep usubjid trtedtm trtedt trtetmf;

run;

```

```
data dm7;

    merge dm6(in=a) ex_start ex_end;

    by usubjid;

    if a;

run;
```

```
data dm8;

    set dm7;

    length trt01pn trt01an 8. trt01p trt01a $40.;

    if randfl="Y" then
        do;

            if armcd="THS 2.2M" then
                trt01pn=4;

            else if armcd="MCC" then
                trt01pn=5;

            else if armcd="SMABST" then
                trt01pn=3;

        end;

    else if randfl ne "Y" then
        do;

            if enfl="Y" then
```



```
        trt01pn=97;
    else if exfl="Y" then
        trt01pn=98;
    else if armcd="SCRNFAIL" then
        trt01pn=99;
    end;
```

If TRT01PN eq 4 then

```
    do
        TRT01P ="THSm2.2";
```

```
    end;
```

else if TRT01PN = 5 then

```
    do;
        TRT01P = "mCC";
```

```
    end;
```

else if TRT01PN = 3 then

```
    do;
        TRT01P ="SA";
```

```
    end;
```

else if TRT01PN = 97 then

```
    TRT01P = "Enrolled not randomized";
```

else if TRT01PN = 98 then

```
    TRT01P = "Exposed but not randomized";
```

else if TRT01PN=99 then

```

        TRT01P='Screen failure';

if dxstdtc ne "" and randfl="N" then

        trt01an=96;

else trt01an=trt01pn;


if trt01an= 4 then

        trt01a="THSm2.2";

else if trt01an= 5 then

        trt01a="mCC";

else if TRT01AN = 3 then

        TRT01A = 'SA';

else if trt01an= 96 then

        trt01a="Product Test";

else if trt01an=99 then

        trt01a='Screen failure';

run;


data icf_t(keep=USUBJID ICF01DTC ICF01DT) icf_b(keep=USUBJID ICF02DTC ICF02DT) icf(keep=USUBJID
ICFDTM ICFDT) rand(keep=usubjid randdt randdtm);

        set ds;

        length ICF01DTC ICF02DTC $20.;

        format ICF01DT ICF02DT ICFDT randdt date9. randdtm ICFDTM datetime13.;

if dscat eq "OTHER EVENT" and dsdecod="INFORMED CONSENT OBTAINED" then

```

```
do;
```

```
if dsterm eq "INFORMED CONSENT FOR TRANSCRIPTOMICS" then
```

```
do;
```

```
ICF01DTC=dsstdtc;
```

```
ICF01DT=input(dsstdtc,yymmdd10.);
```

```
output icf_t;
```

```
end;
```

```
if dsterm eq "INFORMED CONSENT FOR BIOMARKERS" then
```

```
do;
```

```
ICF02DTC=dsstdtc;
```

```
ICF02DT=input(dsstdtc,yymmdd10.);
```

```
output icf_b;
```

```
end;
```

```
end;
```

```
if dscat eq "PROTOCOL MILESTONE" and dsdecod="INFORMED CONSENT OBTAINED" and  
dsterm eq "MAIN INFORMED CONSENT" then
```

```
do;
```

```
if length(dsstdtc)>10 then
```

```
ICFDTM=DHMS(INPUT(SCAN(DSSTDTC,1,'T'),YYMMDD10.),  
HOUR(INPUT(SCAN(DSSTDTC,2,'T'),TIME5.)),  
MINUTE(INPUT(SCAN(DSSTDTC,2,'T'),TIME5.)),0); /* 23) KB 01Jul2014 */
```

```
else if length(dsstdtc)=10 then
```

```
ICFDTM=dhms(input(dsstdtc,yymmdd10.),0,0,0);
```

```
if icfdtm ne . then
```

```

                                icfdt=datepart(icfdtm);
                                output icf;
                                end;

                                if dscat="PROTOCOL MILESTONE" and dsterm="RANDOMIZED" then
                                do;
                                randdtm=input(dsstdtc,is8601dt.);
                                randdt=datepart(randdtm);
                                output rand;
                                end;
run;

data comp(keep=usubjid dsdecod dsterm dsstdtc ) epoch(keep=usubjid epoch);
    set ds;

    if dscat eq "DISPOSITION EVENT" then
        output comp;

    if epoch="FOLLOWUP" then
        output epoch;
run;

proc sort data=epoch nodupkey;by usubjid ;run;

proc sort data=comp;
    by usubjid dsstdtc ;
run;

```

```
data comp_l;
```

```
    set comp ;
```

```
    by usubjid ;
```

```
    if last.usubjid;
```

```
run;
```

```
proc sort data=ds(where=(dsreasp ne "")) out=dsreasp(keep=usubjid dsreasp);
```

```
    by usubjid;
```

```
run;
```

```
data dm9;
```

```
    merge dm8(in=a drop=epoch) icf_t icf_b icf rand epoch comp_l dsreasp;
```

```
    by usubjid;
```

```
    length complfl fupfl $2. dsreas $200.;
```

```
    format discdt date9.;
```

```
    if a;
```

```
    if dsdecod eq "COMPLETED" then
```

```
        complfl="Y";
```

```
    else complfl="N";
```

```
    if dsdecod="LOST TO FOLLOW-UP" then
```

```

        fupfl="N";
    else if epoch="FOLLOWUP" then
        fupfl="Y";
    else if epoch ne "FOLLOWUP" then
        fupfl="N";

    if dsstdtc ne "" then
        discdt = input(dsstdtc,yyymmdd10.);

    if dsdecod in ("SCREEN FAILURE","DEATH","LOST TO FOLLOW-UP","NON COMPLIANCE TO
STUDY PROCEDURE","PHYSICIAN DECISION",
        "PREGNANCY","STUDY TERMINATED BY SPONSOR","TECHNICAL
PROBLEMS","WITHDRAWAL BY SUBJECT","OTHER" "ADVERSE EVENT" "PROTOCOL VIOLATIONS" ) then
        dsreas=strip(dsterm);

run;

/*SV DATES-DISCCAT*/

data sv;

    set sdtm.sv;

run;

proc sort data=sv(where=(visitnum=106)) out=sv106(keep=usubjid svstdy visitnum
rename=(svstdy=svstdy_106 visitnum=visit_106));

    by usubjid;

run;

```

```
proc sort data=sv(where=(visitnum=131)) out=sv131(keep=usubjid svstdy visitnum
rename=(svstdy=svstdy_131 visitnum=visit_131));
```

```
by usubjid;
```

```
run;
```

```
proc sort data=sv(where=(visitnum=161)) out=sv161(keep=usubjid svstdy visitnum
rename=(svstdy=svstdy_161 visitnum=visit_161));
```

```
by usubjid;
```

```
run;
```

```
proc sort data=sv(where=(visitnum=191)) out=sv191(keep=usubjid svstdy visitnum
rename=(svstdy=svstdy_191 visitnum=visit_191));
```

```
by usubjid;
```

```
run;
```

```
* lab data for Biomarkers;
```

```
proc sort data = sdtm.lb(where = (lbcats in ('BIOMARKERS') and missing(lbstat))) out=lb(keep = usubjid)
nodupkey;
```

```
by usubjid;
```

```
run;
```

```
proc sort data=sdtm.dx(where=(epoch="ADMI")) out=dx_1;
```

```
by usubjid dxstdtc;
```

```
where dxstdtc ne "";
```

```
run;
```

```
data dx_2;
```

```

    set dx_1;

    by usubjid dxstdtc;

    if first.usubjid;

    rename dxstdtc=dxstdtc_p;

    keep usubjid dxstdtc;

run;

PROC SORT DATA=SDTM.DX OUT=DX2_(KEEP=USUBJID) NODUPKEY;BY USUBJID ; WHERE DXSTDTC NE "
"; RUN;

data non;

    set sdtm.xp(keep=usubjid )

    sdtm.qs(keep=usubjid)

    sdtm.fa(keep=usubjid);

    flag=1;

run;

proc sort data=non(keep=usubjid flag) nodupkey;

    by usubjid;

run;

data non1;

    set sdtm.lb(keep=usubjid visitnum lbstresc where=(visitnum>=100 and lbstresc ne " "))

    sdtm.eg(keep=usubjid visitnum egstresc where=(visitnum>=100 and egstresc ne " ")) ;

    flag1=1;

run;

proc sort data=non1(keep=usubjid flag1) nodupkey;

    by usubjid;

```



```
run;
```

```
data dm10;
```

```
merge dm9(in=a) sv106 sv131 sv161 sv191 lb(in=b) perf(in=c) dx_2(in=d) non(in=e) DX2_(in=f)  
non1(in=g);
```

```
by usubjid;
```

```
if a;
```

```
length disccat $52. fasfl fsafbfl fsafaf $2. fasreas $200. /*safreas fsafreas*/ FSAFBREA $50.  
FSAFAREA $65.;
```

```
if svstdy_131 eq . then svstdy_131=31;
```

```
if svstdy_161 eq . then svstdy_161=61;
```

```
/*DISCCAT*/
```

```
if enrfl="Y" then
```

```
do;
```

```
if randfl="N" then
```

```
disccat="Discontinued before randomization";
```

```
else if dsdecod="COMPLETED" then
```

```
disccat="Completed";
```

```
else if visit_191 eq . then
```

```
do;
```

```
if trtsdt eq . then
```

```
disccat="Discontinued Period 1 without randomized  
product use";
```

```
else disccat="Discontinued Period 1 with randomized product  
use";
```

```
end;
```

```

else if dsreas ne "" then do;

    if svstdy_191<=svstdy_131 then disccat="Discontinued Period 2";

    else if svstdy_191<=svstdy_161 then disccat="Discontinued Period 3";

    else disccat="Discontinued Period 4";

end;

end;

if b then
do;

    if randfl="Y" then

        do;

            if (armcd eq "THS 2.2M" and epoch_exdx="PRODUCT USE
CONFINEMENT" and trtsdtm ne . ) or (armcd eq "MCC" and epoch_exdx="PRODUCT USE
CONFINEMENT" and trtsdtm ne . )

                or armcd="SMABST" then

                    fasfl="Y";

                else fasfl="N";

            end;

        else fasfl="N";

    if siteid="SEI" then

        fasfl="N";

    end;

else if not b then

```

```

        fasfl="N";
if fasfl='N' then do;
    if missing(icfdt) then
        fasreas1="Did not give informed consent";

    if siteid="SEI" then
        fasreas2="ICH/GCP non-compliance";

    if randfl="N" then
        fasreas3="Was not randomized ";

    if armcd in ("MCC","THSm2.2") then
        do;
            if nmiss(trtsdtm,randdtm)=0 and not (trtsdtm>randdtm) and siteid ne "SEI" then
                fasreas4="Did not have post-randomization smoking event";
        end;

    if not e and siteid^="SEI" then fasreas5="Did not have any valid non-safety post-randomization
assessments";

    fasreas=catx("/",fasreas1,fasreas2,fasreas3,fasreas4,fasreas5);
end;

if f and icfdt ne . then fsafbfl="Y"; else fsafbfl="N";

if fsafbfl="Y" and randfl="Y" and flag1=1 then fsafafl="Y" ;else fsafafl="N" ;

if fsafbfl="Y" and siteid="TOK" then SAFBFL="Y"; else SAFBFL="N";

```

```
if fsafafl="Y" and siteid ="TOK" then SAFAFL="Y"; else SAFAFL="N" ;
```

```
/*FSAFBREA*/
```

```
if fsafbfl="N" then do;
```

```
if missing(icfdt) then FSAFBREA="No informed consent";
```

```
else if not f then FSAFBREA="Not exposed to THS 2.2";
```

```
else FSAFBREA="Reason for exclusion from the Analysis Population";
```

```
end;
```

```
if fsafbfl="N" then FSAFAREA=FSAFBREA;
```

```
else if fsafafl="N" then FSAFAREA="Subjects did not have valid safety assessment post-randomization";
```

```
if fsafbfl="Y" and safbfl="N" then SAFBREA="Site terminated due to ICH/GCP non-compliance";
```

```
if fsafafl="Y" and SAFAFL="N" then SAFAREA="Site terminated due to ICH/GCP non-compliance";
```

```
run;
```

```
/*COMPCP1FL*/
```

```
data ex;
```

```
set sdtm.ex;
```

```
run;
```

```
proc sort data=ex out=ex1a(keep=usubjid) nodupkey;
```

```
by usubjid;
```

```
where (1<=exstdy<=6) and exscat="PRODUCT USE CONFINEMENT";
```

```
run;
```

```
data dx;
```

```
    set sdtm.dx;
```

```
run;
```

```
proc sort data=dx out=dx1a(keep=usubjid) nodupkey;
```

```
    by usubjid;
```

```
    where (1<=dxstdy<=6) and dxscat="PRODUCT USE CONFINEMENT";
```

```
run;
```

```
data su;
```

```
    set sdtm.su;
```

```
run;
```

```
data su_1;
```

```
set su;
```

```
    if index(suscat,"PRODUCT USE DIARY")=0 and sudose>0 and sucate ne "CAFFEINE";
```

```
run;
```

```
proc sort data=su_1 out=su1a(keep=usubjid) nodupkey;
```

```
    by usubjid;
```

```
    where (1<=sustdy<=6);
```

```
run;
```

```
data lb;
```

```
    set sdtm.lb;
```

```
run;
```

```
proc sort data=lb out=lb1(keep=usubjid) nodupkey;

    by usubjid;

    where lbtestcd="CO" and (2<=lbdy<=6) and lbstresn <= 10;

run;
```

```
proc sort data=sv(where=(visitnum=130)) out=sv130(keep=usubjid svenidy visitnum
rename=(svenidy=svenidy_130 visitnum=visit_130));

    by usubjid;

run;
```

```
proc sort data=sv(where=(visitnum=160)) out=sv160(keep=usubjid svenidy visitnum
rename=(svenidy=svenidy_160 visitnum=visit_160));

    by usubjid;

run;
```

```
proc sort data=sv(where=(visitnum=190)) out=sv190(keep=usubjid svenidy visitnum
rename=(svenidy=svenidy_190 visitnum=visit_190));

    by usubjid;

run;
```

```
proc sort data=ex;

    by usubjid;

run;
```

```
data ex_p2;

    merge ex(in=a) sv130 sv160 sv190;
```

```

    by usubjid;

    if a;

    if exdostxt="-9" then
        exdose=0;
    else if exdostxt="-1" then
        exdose=.;

    if sven dy_130 eq . then
        sven dy_130=31;

    if sven dy_160 eq . then
        sven dy_160=61;

    if sven dy_190 eq . then
        sven dy_190=91;
run;

/* CMPCP1FL--CMPCP4FL CMPCOVFL */

proc sql;

    create table base as select usubjid,sum(exdose) as base_dose from ex_p2 where visitnum=100
group by usubjid;

quit;

proc sort data=ex_p2 out=ex1b;

```

```

        by usubjid;

        where (exstdy>=6 and exendy<=svenidy_130) and exscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;

data ex1b1 ex_puc2(keep=usubjid );

    set ex1b;

    if exdose=-9 then

        exdose=0;

    else if exdose=-1 then

        exdose=.;

    stdy=svenidy_130-6+1;

    if exdose>2 then

        output ex_puc2;

    else output ex1b1;

run;

proc sort data=ex_puc2 nodupkey;

    by usubjid;

run;

proc sql;

    create table x as select distinct usubjid,count(usubjid)as count,sum(exdose) as exdose_sum,
stdy,((calculated count)*100/stdy)as per

```



```
        from ex1b1 where usubjid not in(select distinct usubjid from ex_pucacat2 /*ex1b1 where
exdose>2*/) group by usubjid,stdy ;    /*avg_pucacat is used for deriving the pucacat*/
```

```
quit;
```

```
data ex1b3 expucacat2_avg(keep=usubjid avg_) pu2_bi(keep=usubjid avg_bi);
```

```
    merge x(in=a) base;
```

```
    by usubjid;
```

```
    if a;
```

```
    if nmiss(exdose_sum,stdy)=0 then do;
```

```
        avg_bi=round(exdose_sum/stdy,0.01);        /* avg before imputation*/
```

```
    end;
```

```
    if .<avg_bi<0.5 then output pu2_bi;
```

```
    if per <75 then
```

```
        do;
```

```
            if nmiss(exdose_sum,base_dose)=0 then
```

```
                exdose= exdose_sum+base_dose*(stdy-count);
```

```
        end;
```

```
    else exdose=exdose_sum;
```

```
    if nmiss(exdose,count)= 0 then
```

```
        avg_ = exdose/stdy;
```

```
    if avg_<=0.5 then
```

```
        output ex1b3;
```

```

        if avg_>0.5 then
            output expucat2_avg;
run;

proc sort data=ex1b3 out=ex1b3(keep=usubjid ) nodupkey;
    by usubjid;
run;

proc sort data=ex_p2 out=ex_c3;
    by usubjid;
    where (exstdy>svenidy_130 and exendy<=svenidy_160) and exscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER");
run;

data ex_c31 ex_pucat3(keep=usubjid);
    set ex_c3;

    if exdose=-9 then
        exdose=0;
    else if exdose=-1 then
        exdose=.;
    stdy=svenidy_160-svenidy_130+1;

    if exdose>2 then
        output ex_pucat3;
    else output ex_c31;

```

```
run;
```

```
proc sort data=ex_pucac3 nodupkey;
```

```
    by usubjid;
```

```
run;
```

```
proc sql;
```

```
    create table y as select distinct usubjid,count(usubjid)as count,sum(exdose) as  
exdose_sum,stdy,((calculated count)*100/stdy) as per
```

```
    from ex_c31 where usubjid not in(select distinct usubjid from ex_pucac3 /*ex_c31  
where exdose>2*/) group by usubjid,stdy;
```

```
quit;
```

```
data ex_c32 expucac3_avg(keep=usubjid avg_) pu3_bi(keep=usubjid);
```

```
    merge y(in=a) base;
```

```
    by usubjid;
```

```
    if a;
```

```
        if nmiss(exdose_sum,stdy)=0 then do;
```

```
            avg_bi=round(exdose_sum/stdy,0.01);          /* avg before imputation*/
```

```
        end;
```

```
        if .<avg_bi<0.5 then output pu3_bi;
```

```
        if per <75 then
```

```
            do;
```

```
                if nmiss(exdose_sum,base_dose)=0 then
```

```
                    exdose= exdose_sum+base_dose*(stdy-count);
```

```

        end;

    else exdose=exdose_sum;

    if nmiss(exdose,count)= 0 then

        avg_ = exdose/stdy;

    if avg_<=0.5 then

        output ex_c32;

    if avg_>0.5 then

        output expucat3_avg;

run;

proc sort data=ex_c32 out=ex_c33(keep=usubjid ) nodupkey;

    by usubjid;

run;

proc sort data=ex_p2 out=ex_c4;

    by usubjid;

    where (exstdy>svendy_160 and exendy<=svendy_190) and exscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;

data ex_c41 ex_pucat4(keep=usubjid);

    set ex_c4;

    if exdose=-9 then

```

```

        exdose=0;
    else if exdose=-1 then
        exdose=.;
    stdy=svendy_190-svendy_160+1;

    if exdose>2 then
        output ex_pucat4;
    else output ex_c41;
run;

```

```

data diff4;

set ex_c41;

diffday=dif(exstdy);

if diffday>7 then flag_=1;

run;

```

```

proc sql;

    create table z as select distinct usubjid,count(usubjid)as count,sum(exdose) as
    exdose_sum,stdy,((calculated count)*100/stdy)

        as per from ex_c41 where usubjid not in(select distinct usubjid from ex_pucat4)group
    by usubjid,stdy;

quit;

proc sort data=diff4(keep=usubjid flag_) nodupkey;by usubjid; where flag_ eq 1 ; run;

```

```

data ex_c42 expucat4_avg(keep=usubjid avg_) pu4_bi(keep=usubjid);

    merge z(in=a) base diff4;

    by usubjid;

    if a;

    if nmiss(exdose_sum,stdy)=0 then do;

        avg_bi=round(exdose_sum/stdy,0.01);          /* avg before impuation*/

    end;

    if .<avg_bi<0.5 then output pu4_bi;

    if per <75 or flag_=1 then

        do;

            if nmiss(exdose_sum,base_dose)=0 then

                exdose= exdose_sum+base_dose*(stdy-count);

            end;

        else exdose=exdose_sum;

    if nmiss(exdose,count)= 0 then

        avg_ = exdose/stdy;

    if avg_<=0.5 then

        output ex_c42;

    if avg_>0.5 then

        output expucat4_avg;

```

```
run;
```

```
proc sort data=ex_c42 out=ex_c43(keep=usubjid ) nodupkey;
```

```
    by usubjid;
```

```
run;
```

```
proc sort data=ex_pucat4 nodupkey;
```

```
    by usubjid;
```

```
run;
```

```
proc sort data=ex_p2 out=ex_c5;
```

```
    by usubjid;
```

```
    where (exstdy>6 and exendy<=svenidy_190) and exscat in ("PRODUCT USE DIARY -  
ELECTRONIC","PRODUCT USE DIARY - PAPER");
```

```
run;
```

```
data ex_c51 ex_pucat5(keep=usubjid);
```

```
    set ex_c5;
```

```
    if exdose=-9 then
```

```
        exdose=0;
```

```
    else if exdose=-1 then
```

```
        exdose=.;
```

```
    stdy=svenidy_190-6+1;
```

```
    if exdose>2 then
```

```
        output ex_pucat5;
```

```

        else output ex_c51;

run;

data diff;

set ex_c51;

diffday=dif(exstdy);

if diffday>7 then flag_=1;

run;

proc sort data=diff(keep=usubjid flag_) nodupkey;by usubjid; where flag_ eq 1 ; run;

proc sql;

        create table z1 as select distinct usubjid,count(usubjid)as count,sum(exdose) as
        exdose_sum,stdy,((calculated count)*100/stdy)

                as per from ex_c51 where  usubjid not in(select distinct usubjid from
        ex_pucat5/*ex_c51 where exdose>2*/)group by usubjid,stdy;

quit;


data ex_c52  expucat5_avg(keep=usubjid avg_) pu5_bi(keep=usubjid);

        merge z1(in=a) base diff;

        by usubjid;

        if a;

        if nmiss(exdose_sum,stdy)=0 then do;

                avg_bi=round(exdose_sum/stdy,0.01);                /* avg before impuation*/

        end;

        if .<avg_bi<0.5 then output pu5_bi;

```



```

if per <75 or flag_ eq 1 then do;
    if nmiss(exdose_sum,base_dose)=0 then
        exdose= exdose_sum+base_dose*(stdy-count);
    end;
else exdose=exdose_sum;

if nmiss(exdose,count)= 0 then
    avg_ = exdose/stdy;

if avg_<=0.5 then
    output ex_c52;

if avg_>0.5 then
    output expucat5_avg;
run;

proc sort data=ex_c52 out=ex_c53(keep=usubjid ) nodupkey;
    by usubjid;
run;

proc sort data=ex_pucat5 nodupkey;
    by usubjid;
run;

data dm11;

```

```
merge dm10(in=a) ex1a(in=b) dx1a(in=c) su1a(in=d) lb1(in=e) ex1b3(in=f) ex_c33(in=g)
ex_c43(in=h) base;
```

```
by usubjid;
```

```
length cmpcp1fl cmpcp2fl cmpcp3fl cmpcp4fl cmpcovfl $2.;
```

```
if fasfl="Y" then
```

```
do;
```

```
if trt01p="THSm2.2" and not(b /*or d*/) then
```

```
    cmpcp1fl="Y";
```

```
else cmpcp1fl="N";
```

```
if trt01p="mCC" then
```

```
    cmpcp1fl="Y";
```

```
if trt01p="SA" then
```

```
do;
```

```
    if not (c or b /*or d*/) and e then
```

```
        cmpcp1fl="Y";
```

```
else cmpcp1fl="N";
```

```
end;
```

```
end;
```

```
else if fasfl="N" then
```

```
    cmpcp1fl="N";
```

```
if fasfl="Y" then
```

```
do;

    if trt01p in ("THSm2.2","SA") and f then

        cmpcp2fl="Y";

    else if trt01p="mCC" then

        cmpcp2fl="Y";

    else cmpcp2fl="N";

end;

else if fasfl="N" then

    cmpcp2fl="N";

if fasfl="Y" then

    do;

        if trt01p in ("THSm2.2","SA") and g then

            cmpcp3fl="Y";

        else if trt01p="mCC" then

            cmpcp3fl="Y";

        else cmpcp3fl="N";

    end;

else if fasfl="N" then

    cmpcp3fl="N";

if fasfl="Y" then

    do;

        if trt01p in ("THSm2.2","SA") and h then

            cmpcp4fl="Y";
```

```

        else if trt01p="mCC" then
            cmpcp4fl="Y";
        else cmpcp4fl="N";
    end;

    else if fasfl="N" then
        cmpcp4fl="N";
    if DISCCAT = "Discontinued Period 1 with randomized product use" then do;
    if trt01p in ("THSm2.2","SA") and base_dose>0 then cmpcp1fl="N";

    cmpcp2fl="N";
    cmpcp3fl="N";
    cmpcp4fl="N";
    end;

    else if DISCCAT in( "Discontinued Period 2") then do;
    cmpcp3fl="N";
    cmpcp4fl="N";
    end;

    else if DISCCAT in("Discontinued Period 3"/*,"Discontinued Period 4"*/) then do;
    cmpcp4fl="N";
    end;

        if cmpcp1fl=cmpcp2fl=cmpcp3fl=cmpcp4fl="Y" then
            cmpcovfl="Y";
        else cmpcovfl="N";
run;

```

```
proc sort data=sdtm.dv out=dv1; by usubjid ; run;
```

```
proc sort data=sdtm.suppdv out=suppdv; by usubjid idvarval; where qnam="EVALCAT";run;
```

```
proc transpose data=suppdv out=suppdv_(drop=_name__label_);
```

```
by usubjid idvarval;
```

```
var qval;
```

```
id qnam;
```

```
run;
```

```
proc sql;
```

```
create table dv1a as select a.*,b.evalcat from dv1 a left join suppdv_ b on a.usubjid=b.usubjid and  
a.dvseq=input(b.idvarval,best.);
```

```
quit;
```

```
data dv(where=(EVALCAT="NON EVALUABLE"));
```

```
merge dv1a(in=a) sv130 sv160 sv190;
```

```
by usubjid;
```

```
if a;
```

```
if svenidy_130 eq . then
```

```
    svenidy_130=31;
```

```
if svenidy_160 eq . then
```

```
    svenidy_160=61;
```

```

        if svenidy_190 eq . then

            svenidy_190=91;

run;

/* as per john email if the subject has dvcat in("MIS-RANDOMIZATION","VIOLATION") and
EVALCAT="NON EVALUABLE" then subject has value PPROT1FL-PPROT4FL=N */

proc sort data=dv out=dv_all(keep=usubjid) nodupkey ; by usubjid;

where dvcat in("MIS-RANDOMIZATION","VIOLATION") and EVALCAT="NON EVALUABLE";

run;

proc sort data=dv out=dv_p1(keep=usubjid dvcat rename=(dvcat=dvcat_p1)) nodupkey;

        by usubjid;                                /*DVCAT is has missing value in source DV so we
consider if subject is present in DV they will be consider as deviation subjects*/

        where UPCASE(dvcat) in ("MIS-RANDOMIZATION","MIS-USE OF
PRODUCT","VIOLATION","DURATION OF 24 HOUR COLLECTION") and (1<=dvstdy<=6);

RUN;

proc sort data=dv out=dv_p2(keep=usubjid dvcat rename=(dvcat=dvcat_p2)) nodupkey;

        by usubjid;

        where UPCASE(dvcat) in ("MIS-RANDOMIZATION","MIS-USE OF
PRODUCT","VIOLATION","DURATION OF 24 HOUR COLLECTION") and (6<=dvstdy<=svenidy_130);

RUN;

proc sort data=dv out=dv_p3(keep=usubjid dvcat rename=(dvcat=dvcat_p3)) nodupkey;

        by usubjid;

        where UPCASE(dvcat) in ("MIS-RANDOMIZATION","MIS-USE OF
PRODUCT","VIOLATION","DURATION OF 24 HOUR COLLECTION") and
(svenidy_130<dvstdy<=svenidy_160);

```

```
RUN;
```

```
proc sort data=dv out=dv_p4(keep=usubjid dvcate rename=(dvcate=dvcate_p4)) nodupkey;
```

```
by usubjid;
```

```
where UPCASE(dvcate) in ("MIS-RANDOMIZATION","MIS-USE OF  
PRODUCT","VIOLATION","DURATION OF 24 HOUR COLLECTION") and  
(svenydy_160<dvstdy<=svenydy_190);
```

```
RUN;
```

```
proc import out=pd datafile="dev/meta/final 07 PDs_03June2015_AL comments.xls"
```

```
DBMS=xls REPLACE ;
```

```
GETNAMES=Yes;
```

```
run;
```

```
data pd1a;
```

```
set pd(rename=(usubjid=usubjid_));
```

```
length usubjid $24. ;
```

```
usubjid=strip(usubjid_);
```

```
where incl="Yes" and upcase(pdcat) in ('MIS-RANDOMIZATION','VIOLATION','MIS-USE OF PRODUCT',  
'DURATION OF 24 HOUR COLLECTION')
```

```
and pdeval='Non-Evaluable'
```

```
;
```

```
keep usubjid incl visit visitnum pdstdat_raw pdendat_raw pdcat;
```

```
run;
```

```
proc sql;
```

```
create table pd_fin as select a.*,b.randdt from pd1a a left join
```

```
dm11 b on a.usubjid=b.usubjid;
```

```

quit;

data pd_fin1;

set pd_fin;

pddy=input(pdstdat_raw,date9.)-randdt;

run;

data pd1;

    merge pd_fin1(in=a) sv130 sv160 sv190;

    by usubjid;


    if a;


    if svenidy_130 eq . then

        svenidy_130=31;


    if svenidy_160 eq . then

        svenidy_160=61;


    if svenidy_190 eq . then

        svenidy_190=91;

run;

proc sort data=pd1 out=pd_p1(keep=usubjid pdcats rename=(pdcats=pdcats_p1)) nodupkey;

    by usubjid;                                /*DVCAT is has missing value in source DV so we
consider if subject is present in DV they will be consider as deviation subjects*/

    where (1<=pddy<=6);

RUN;

```



```
proc sort data=pd1 out=pd_p2(keep=usubjid pdcats rename=(pdcats=pdcats_p2) ) nodupkey;

    by usubjid;

    where (6<=pddy<=svely_130);
```

```
RUN;
```

```
proc sort data=pd1 out=pd_p3(keep=usubjid pdcats rename=(pdcats=pdcats_p3)) nodupkey;

    by usubjid;

    where (svely_130<pddy<=svely_160);
```

```
RUN;
```

```
proc sort data=pd1 out=pd_p4(keep=usubjid pdcats rename=(pdcats=pdcats_p4)) nodupkey;

    by usubjid;

    where (svely_160<pddy<=svely_190);
```

```
RUN;
```

```
data dm12;
```

```
    merge dm11(in=a) dv_p1(in=b) dv_p2(in=c) dv_p3(in=d) dv_p4(in=e) pd_p1(in=f) pd_p2(in=g)
pd_p3(in=h) pd_p4(in=i) dv_all(in=j);
```

```
    by usubjid;
```

```
    if a;
```

```
    length pprot1fl pprot2fl pprot3fl pprot4fl $2. ppreas1-ppreas4 $200.;
```

```
    if fasfl="Y" and cmpcp1fl="Y" and not (b or f or j) then
```

```
        pprot1fl="Y";
```

```
    else pprot1fl="N";
```

```
if fasfl="Y" and cmpcp2fl="Y" and not( c or g or j)then
```

```
    pprot2fl="Y";
```

```
else pprot2fl="N";
```

```
if fasfl="Y" and cmpcp3fl="Y" and not (d or h or j)then
```

```
    pprot3fl="Y";
```

```
else pprot3fl="N";
```

```
if fasfl="Y" and cmpcp4fl="Y" and not (e or i or j)then
```

```
    pprot4fl="Y";
```

```
else pprot4fl="N";
```

```
if fasfl="N" then
```

```
    do;
```

```
        ppreas1="Not in FAS";
```

```
        ppreas2="Not in FAS";
```

```
        ppreas3="Not in FAS";
```

```
        ppreas4="Not in FAS";
```

```
    end;
```

```
else if fasfl="Y" then
```

```
    do;
```

```
        if upcase(dvcat_p1)="PRODUCT COMPLIANCE" or cmpcp1fl="N" then
```

```
            ppreas1="Has major protocol deviations not compliant";
```

```
        else if j or dvcat_p1 ne " " or pdcat_p1 ne " " then
```

```

        ppreas1="Has other major protocol deviations impacting evaluability";

if upcase(dvcat_p2)="PRODUCT COMPLIANCE" or cmpcp2fl="N" then
    ppreas2="Has major protocol deviations not compliant";
else if j or dvcat_p2 ne " " or pdcat_p2 ne " " then
    ppreas2="Has other major protocol deviations impacting evaluability";

if upcase(dvcat_p3)="PRODUCT COMPLIANCE" or cmpcp3fl="N" then
    ppreas3="Has major protocol deviations not compliant";
else if j or dvcat_p3 ne " " or pdcat_p3 ne " " then
    ppreas3="Has other major protocol deviations impacting evaluability";

if upcase(dvcat_p4)="PRODUCT COMPLIANCE" or CMPCP4FL="N" then
    ppreas4="Has major protocol deviations not compliant";
else if j or dvcat_p4 ne " " or pdcat_p4 ne " " then
    ppreas4="Has other major protocol deviations impacting evaluability";

end;

if disccat eq "Discontinued Period 1 with randomized product use" and pprot2fl="N" and ppreas2 ne
"Not in FAS" then ppreas2="Discontinued in previous period";

if disccat in ("Discontinued Period 2","Discontinued Period 1 with randomized product use") and
ppreas3 ne "Not in FAS" and pprot3fl="N" then ppreas3="Discontinued in previous period";

if disccat in ("Discontinued Period 3" ,"Discontinued Period 2","Discontinued Period 1 with randomized
product use") and ppreas4 ne "Not in FAS" and pprot4fl="N" then ppreas4="Discontinued in previous
period";

drop dvcat_p;;

run;

```

```
/* COMPP1FL---COMPP4FL*/
```

```
proc sort data=dx;
```

```
    by usubjid;
```

```
run;
```

```
data dx_p2;
```

```
    merge dx(in=a) sv130 sv160 sv190;
```

```
    by usubjid;
```

```
    if a;
```

```
    if svenidy_130 eq . then
```

```
        svenidy_130=31;
```

```
    if svenidy_160 eq . then
```

```
        svenidy_160=61;
```

```
    if svenidy_190 eq . then
```

```
        svenidy_190=91;
```

```
run;
```

```
proc sort data=su;
```

```
    by usubjid;
```

```
run;
```

```
data su_p2;

    merge su(in=a) sv130 sv160 sv190;

    by usubjid;

    if a;

    if sven dy_130 eq . then
        sven dy_130=31;

    if sven dy_160 eq . then
        sven dy_160=61;

    if sven dy_190 eq . then
        sven dy_190=91;

run;


proc sort data=lb out=lb1;

    by usubjid;

    where lbtestcd="CO" and lbstresn<=10;

run;


data lb_p2;

    merge lb1(in=a) sv130 sv160 sv190;

    by usubjid;
```

```

if a;

if sven dy_130 eq . then
    sven dy_130=31;

if sven dy_160 eq . then
    sven dy_160=61;

if sven dy_190 eq . then
    sven dy_190=91;

run;

proc sort data=ex_p2 out=ex_cp2(keep=usubjid ) nodupkey;
    by usubjid;
    where (exstdy>=6 and exendy<=sven dy_130) and exscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER") and exdose>0;
run;

proc sort data=ex_p2 out=ex_cp3 (keep=usubjid ) nodupkey;
    by usubjid;
    where (exstdy>sven dy_130 and exendy<=sven dy_160) and exdose>0 and exscat in ("PRODUCT
USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER");
run;

proc sort data=ex_p2 out=ex_cp4 (keep=usubjid) nodupkey;

```

```
by usubjid;

where (exstdy>svendy_160 and exendy<=svendy_190) and exdose>0 and exscat in ("PRODUCT
USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;
```

```
proc sort data=dx_p2 out=dx_cp2(keep=usubjid ) nodupkey;
```

```
by usubjid;

where (6<=dxstdy and dxendy<=svendy_130) and dxscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER") and dxdose>0;

run;
```

```
proc sort data=dx_p2 out=dx_cp3 (keep=usubjid ) nodupkey;
```

```
by usubjid;

where (svendy_130<dxstdy and dxendy<=svendy_160) and dxdose>0 and dxscat in ("PRODUCT
USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;
```

```
proc sort data=dx_p2 out=dx_cp4 (keep=usubjid ) nodupkey;
```

```
by usubjid;

where (svendy_160<dxstdy and dxendy<=svendy_190) and dxdose>0 and dxscat in ("PRODUCT
USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;
```

```
proc sort data=su_p2 out=su_cp2(keep=usubjid ) nodupkey;
```

```
by usubjid;

where (6<=sustdy<=svendy_130) and sucat ne "NRT_USE" and suscat in ("PRODUCT USE DIARY -
PAPER","PRODUCT USE DIARY - ELECTRONIC") and sudose>0;
```

```
run;
```

```
proc sort data=su_p2 out=su_cp3 (keep=usubjid ) nodupkey;
```

```
by usubjid;
```

```
where (svenidy_130<sustdy<=svenidy_160) and sudose>0 and sucat ne "NRT_USE" and suscat in  
("PRODUCT USE DIARY - PAPER","PRODUCT USE DIARY - ELECTRONIC");
```

```
run;
```

```
proc sort data=su_p2 out=su_cp4 (keep=usubjid) nodupkey;
```

```
by usubjid;
```

```
where (svenidy_160<sustdy<=svenidy_190) and sudose>0 and sucat ne "NRT_USE" and suscat in  
("PRODUCT USE DIARY - PAPER","PRODUCT USE DIARY - ELECTRONIC");
```

```
run;
```

```
proc sort data=lb_p2 out=lb_cp2(keep=usubjid ) nodupkey;
```

```
by usubjid;
```

```
where (6<=lbdy<=svenidy_130);
```

```
run;
```

```
proc sort data=lb_p2 out=lb_cp3 (keep=usubjid ) nodupkey;
```

```
by usubjid;
```

```
where (svenidy_130<lbdy<=svenidy_160);
```

```
run;
```

```
proc sort data=lb_p2 out=lb_cp4 (keep=usubjid ) nodupkey;
```

```
by usubjid;
```



```

        where (svendy_160<lbdy<=svendy_190);

run;

data dm13a;

        merge dm12(in=a keep=usubjid pprot2fl trt01p ) ex_cp2(in=b) dx_cp2(in=c) su_cp2(in=d)
lb_cp2(in=e);

        by usubjid;

        if a;

        if b then

                flag_ex=1;

        if c then

                flag_dx=1;

        if d then

                flag_su=1;

        if e then

                flag_lb=1;

length comp2fl $2.;

        if PPROT2FL="Y" then

                do;

                        if trt01p="THSm2.2" then

```

```

do;
    if N(flag_ex ,flag_su )=0 then
        compp2fl="Y";
    end;

if trt01p="mCC" then
    do;
        if N(flag_su,flag_dx)=0 then
            compp2fl="Y";
        end;

if trt01p="SA" then
    do;
        if N(flag_dx ,flag_su,flag_ex )=0 and flag_lb eq 1 then
            compp2fl="Y";
        end;

if compp2fl^="Y" then
    compp2fl="N";
end;
else if pprot2fl="N" then
    compp2fl="N";
keep usubjid compp2fl;
run;

```

```

data dm13b;

    merge dm12(in=a keep=usubjid pprot3fl trt01p ) ex_cp3(in=b) dx_cp3(in=c) su_cp3(in=d)
lb_cp3(in=e);

    by usubjid;

    if a;

    length comp3fl $2.;

    if b then

        flag_ex=1;

    if c then

        flag_dx=1;

    if d then

        flag_su=1;

    if e then

        flag_lb=1;

    if pprot3fl="Y" then

        do;

            if trt01p="THSm2.2" then

                do;

                    if N(flag_ex,flag_su)=0 then

                        comp3fl="Y";

```

```

end;

if trt01p="mCC" then
    do;
        if N(flag_su,flag_dx)=0 then
            comp3fl="Y";
        end;
    end;

if trt01p="SA" then
    do;
        if N(flag_dx ,flag_su,flag_ex )=0 and flag_lb eq 1 then
            comp3fl="Y";
        end;
    end;

if comp3fl^="Y" then
    comp3fl="N";
end;

else if pprot3fl="N" then
    comp3fl="N";
    keep usubjid comp3fl;
run;

data dm13c;

    merge dm12(in=a keep=usubjid pprot4fl trt01p ) ex_cp4(in=b) dx_cp4(in=c) su_cp4(in=d)
    lb_cp4(in=e);

    by usubjid;

```

if a;

length comp4fl \$2.;

if b then

flag_ex=1;

if c then

flag_dx=1;

if d then

flag_su=1;

if e then

flag_lb=1;

if pprot4fl="Y" then

do;

if trt01p="THSm2.2" then

do;

if N(flag_ex,flag_su)=0 then

comp4fl="Y";

end;

if trt01p="mCC" then

```

do;
    if N(flag_su,flag_dx)=0 then
        compp4fl="Y";
    end;

if trt01p="SA" then
    do;
        if N(flag_dx ,flag_su,flag_ex )=0 and flag_lb eq 1 then
            compp4fl="Y";
        end;

        if compp4fl^="Y" then
            compp4fl="N";
        end;
    end;
else if pprot4fl="N" then
    compp4fl="N";
keep usubjid compp4fl;
run;

data dm13;

    merge dm12(in=a) dm13a dm13b dm13c;

    by usubjid;

    length compp1fl cmppovfl $2.;

    compp1fl=pprot1fl;

```

```
    if compp1fl=compp2fl=compp3fl=compp4fl="Y" then
        cmppovfl="Y";
    else cmppovfl="N";
run;
```

```
data ex_p3;
    set ex_p2;
```

```
    if exdose=-9 then
        exdose=0;
    else if exdose=-1 then
        delete;

run;
```

```
data dx_p2;
    set dx_p2;

    if dxdostxt="-9" then dxdose=0;
    else if dxdostxt="-1" then delete;
```

```
run;
```

```
data su_p2;
    set su_p2;

    if sudostxt="-9" then sudose=0;
```

```
else if sudostxt="-1" then delete;
```

```
run;
```

```
/*FOR PUCAT derivation of THS */
```

```
/*period 2*/
```

```
proc sort data=su_p2 out=su_n2;
```

```
by usubjid;
```

```
where (sustdy>=6 and sustdy<=svendy_130) and sudose>0 and suscat in ("PRODUCT  
USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and sucate ne "CAFFEINE";
```

```
run;
```

```
proc sql;
```

```
create table su_p2ths as select distinct usubjid,count(usubjid)as count,max(sudose) as  
max,
```

```
sum(sudose)as sudose_sum, ((calculated sudose_sum)/calculated count)as  
avg_su from su_n2
```

```
group by usubjid ;
```

```
quit;
```

```
/*period 3*/
```

```
proc sort data=su_p2 out=su_n3;
```

```
by usubjid;
```

```
where (svendy_130<sustdy<=svendy_160) and sudose>0 and suscat in ("PRODUCT USE  
DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and sucate ne "CAFFEINE";
```

```
run;
```

```
proc sql;
```



```

        create table su_p3ths as select distinct usubjid,count(usubjid)as count,max(sudose) as
max,
        sum(sudose)as sudose_sum, ((calculated sudose_sum)/calculated count)as
avg_su from su_n3
        group by usubjid ;

quit;

/*period 4*/

proc sort data=su_p2 out=su_n4;

        by usubjid;

        where (svendy_160<sustdy<=svendy_190) and sudose>0 and suscat in ("PRODUCT USE
DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and sucate ne "CAFFEINE";

run;

proc sql;

        create table su_p4ths as select distinct usubjid,count(usubjid)as count,max(sudose) as
max,
        sum(sudose)as sudose_sum, ((calculated sudose_sum)/calculated count)as
avg_su from su_n4
        group by usubjid ;

quit;

/*period 5*/

proc sort data=su_p2 out=su_n5;

        by usubjid;

        where (6<=sustdy<=svendy_190) and sudose>0 and suscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER") and sucate ne "CAFFEINE";

run;

```

```

proc sql;

        create table su_p5ths as select distinct usubjid,count(usubjid)as count,max(sudose) as
max,

        sum(sudose)as sudose_sum, ((calculated sudose_sum)/calculated count)as
avg_su from su_n5

        group by usubjid ;

quit;

```

```

        /*FOR PUCAT derivation of THS NON NRT use */

/*period 2*/

proc sort data=su_p2 out=su_n2n;

        by usubjid;

        where (sustdy>=6 and sustdy<=svendy_130) and sudose>0 and suscat in ("PRODUCT
USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and

        suscat not in ('NRT_USE' 'CAFFEINE');

run;

```

```

proc sql;

        create table su_p2thsnrt as select distinct usubjid,count(usubjid)as count,max(sudose)
as max_nonrt,

        sum(sudose)as sudose_sum, ((calculated sudose_sum)/calculated count)as
avg_su_nonrt from su_n2n

        group by usubjid ;

quit;

/*period 3*/

proc sort data=su_p2 out=su_n3n;

```

```
        by usubjid;

        where (svenidy_130<sustdy<=svenidy_160) and sudose>0 and suscat in ("PRODUCT USE
DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER")

and  suscat not in ('NRT_USE' 'CAFFEINE');
```

```
run;
```

```
proc sql;
```

```
        create table su_p3thsnrt as select distinct usubjid,count(usubjid)as count,max(sudose)
as max_nonrt,
```

```
        sum(sudose)as sudose_sum, ((calculated sudose_sum)/calculated count)as
avg_su_nonrt from su_n3n
```

```
        group by usubjid ;
```

```
quit;
```

```
/*period 4*/
```

```
proc sort data=su_p2 out=su_n4n;
```

```
        by usubjid;
```

```
        where (svenidy_160<sustdy<=svenidy_190) and sudose>0 and suscat in ("PRODUCT USE
DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and
```

```
        suscat not in ('NRT_USE' 'CAFFEINE');
```

```
run;
```

```
proc sql;
```

```
        create table su_p4thsnrt as select distinct usubjid,count(usubjid)as count,max(sudose)
as max_nonrt,
```

```
        sum(sudose)as sudose_sum, ((calculated sudose_sum)/calculated count)as
avg_su_nonrt from su_n4n
```

```

        group by usubjid ;

quit;

/*period 5*/

proc sort data=su_p2 out=su_n5n;

    by usubjid;

    where (6<=sustdy<=svendy_190) and sudose>0 and suscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER") and

sucat not in ('NRT_USE' 'CAFFEINE');

run;

proc sql;

    create table su_p5thsnrt as select distinct usubjid,count(usubjid)as count,max(sudose)
as max_nonnrt,

    sum(sudose)as sudose_sum, ((calculated sudose_sum)/calculated count)as
avg_su_nonnrt from su_n5n

    group by usubjid ;

quit;

proc sql;

    create table ex_pu1 as select usubjid,sum(exdose) as ex_pu1 from ex_p3 where
(6<=exstdy<=svendy_190) and exscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY -
PAPER") group by usubjid;

    create table dx_pu1 as select usubjid,sum(dxdose) as dx_pu1 from dx_p2 where
(6<=dxstdy<=svendy_190) and dxscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY -
PAPER") group by usubjid;

```

```
create table dx_pu2 as select usubjid,sum(dxdose) as dx_pu2 from dx_p2 where
(6<=dxstdy<=svenidy_130) and dxscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY -
PAPER") group by usubjid;
```

```
create table dx_pu3 as select usubjid,sum(dxdose) as dx_pu3 from dx_p2 where
(svenidy_130<dxstdy<=svenidy_160) and dxscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE
DIARY - PAPER") group by usubjid;
```

```
create table dx_pu4 as select usubjid,sum(dxdose) as dx_pu4 from dx_p2 where
(svenidy_160<dxstdy<=svenidy_190) and dxscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE
DIARY - PAPER") group by usubjid;
```

```
create table dx_pu5 as select usubjid,sum(dxdose) as dx_pu5 from
dx_p2 where (6<=dxstdy<=svenidy_190) and dxscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT
USE DIARY - PAPER") group by usubjid;
```

```
create table su_pu1 as select usubjid,sum(sudose)
as su_pu1,svenidy_190 from su_p2 where (6<=sustdy<=svenidy_190) and sucate ne "NRT_USE" and suscate
in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") group by usubjid,svenidy_190;
```

```
create table su_pu2 as select usubjid,sum(sudose) as su_pu2,svenidy_130 from su_p2 where
(6<=sustdy<=svenidy_130) and suscate in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY -
PAPER") group by usubjid,svenidy_130;
```

```
create table su_pu3 as select usubjid,sum(sudose) as su_pu3,svenidy_160 from su_p2 where
(svenidy_130<sustdy<=svenidy_160) and suscate in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE
DIARY - PAPER") group by usubjid,svenidy_160;
```

```
create table su_pu4 as select usubjid,sum(sudose) as su_pu4 from su_p2 where
(svenidy_160<sustdy<=svenidy_190) and suscate in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE
DIARY - PAPER") group by usubjid;
```

```
create table su_pu5 as select usubjid,sum(sudose) as su_pu5 from su_p2 where
(6<=sustdy<=svenidy_190) and suscate in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY -
PAPER") group by usubjid;
```

```
quit;
```

```
/* NEED TO UPDATE FROM HERE*/
```

```
%macro pucat(out1=,svdy=, svenidy=, out2=, out3=, ex_pu=, finout=);
```

```

proc sort data=ex_p3 out=&out1.;
    by usubjid;
    where (exstdy>&svdy. and exendy<=&svendy.) and exscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER");
run;

data &out2.;
    set &out1.;
    stdy=(&svendy.-&svdy.);
run;

data x;
    set &out2.;
    diffday=dif(exstdy);
    if diffday>7 then flag=1;
run;

proc sort data=x(keep=usubjid flag) nodupkey; by usubjid ; where flag=1;run;

proc sql;
    create table &out3. as select distinct usubjid,count(usubjid)as count,
    sum(exdose)as exdose_sum,stdy,((calculated count)*100/stdy)as per from
&out2.
    group by usubjid,stdy ;
quit;

data &finout.(keep=usubjid &ex_pu flag_sa);
    merge &out3.(in=a) base x;

```

```

        by usubjid;

        if a;

        if per <75 or flag=1 then do;

        flag_sa=1;

                if nmiss(exdose_sum,base_dose)=0 then

                        &ex_pu.=exdose_sum+base_dose*(stdy-count);

                end;

        else &ex_pu.=exdose_sum;

run;

%mend;

%macro pucat5(out1= ,svdy= , svenidy= , out2=, out3= , ex_pu= , finout=);

proc sort data=ex_p3 out=&out1.;

        by usubjid;

        where (exstdy>=&svdy. and exendy<=&svenidy.) and exscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;

data &out2.;

        set &out1.;

        stdy=(&svenidy.-&svdy.)+1;

run;

```

```

data x;

set &out2.;

        diffday=dif(exstdy);

    if diffday>7 then flag=1;

run;

        proc sort data=x(keep=usubjid flag) nodupkey; by usubjid ; where flag=1;run;


proc sql;

    create table &out3. as select distinct usubjid,count(usubjid)as count,

        sum(exdose)as exdose_sum,stdy,((calculated count)*100/stdy)as per from
&out2.

        group by usubjid,stdy ;

quit;


data &finout.(keep=usubjid &ex_pu flag_sa);

    merge &out3.(in=a) base x;

    by usubjid;


    if a;


    if per <75 or flag=1 then        do;

        flag_sa=1;

        if nmiss(exdose_sum,base_dose)=0 then

            &ex_pu.=exdose_sum+base_dose*(stdy-count);

        end;

    else &ex_pu.=exdose_sum;

```



```

run;

%mend;

%pucac(out1=ex_pu3a,svdy=svendy_130,
svendy=svendy_160,out2=ex_pu3b,out3=ex_pu3c,ex_pu=ex_pu3,finout=ex_pu3);

%pucac(out1=ex_pu4a,svdy=svendy_160,
svendy=svendy_190,out2=ex_pu4b,out3=ex_pu4c,ex_pu=ex_pu4,finout=ex_pu4);

%pucac5(out1=ex_pu5a,svdy=6,
svendy=svendy_190,out2=ex_pu5b,out3=ex_pu5c,ex_pu=ex_pu5,finout=ex_pu5);

proc sort data=ex_p3 out=ex_pu2a;

    by usubjid;

    where (exstdy>=6 and exendy<=svendy_130) and exscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;

data ex_pu2b;

    set ex_pu2a;

    stdy=svendy_130-6+1;

run;

proc sql;

    create table x1 as select distinct usubjid,count(usubjid)as count,

        sum(exdose)as exdose_sum,stdy,((calculated count)*100/stdy)as per from ex_pu2b

    group by usubjid, stdy;

```

```
quit;
```

```
proc sort data=ex_p3 out=ex_pu2a;
```

```
    by usubjid;
```

```
    where (exstdy>=6 and exendy<=svenidy_130) and exscat in ("PRODUCT USE DIARY -  
ELECTRONIC","PRODUCT USE DIARY - PAPER");
```

```
run;
```

```
data ex_pu2b;
```

```
    set ex_pu2a;
```

```
    stdy=svenidy_130-6+1;
```

```
run;
```

```
proc sql;
```

```
    create table x1 as select distinct usubjid,count(usubjid)as count,
```

```
        sum(exdose)as exdose_sum,stdy,((calculated count)*100/stdy)as per from ex_pu2b
```

```
    group by usubjid, stdy;
```

```
quit;
```

```
data ex_pu2(keep=usubjid ex_pu2 flag_sa);
```

```
    merge x1(in=a) base;
```

```
    by usubjid;
```

```
    if a;
```

```
    if per <75 then do;
```

```

        flag_sa=1;

        if nmiss(exdose_sum,base_dose)=0 then

            ex_pu2=exdose_sum+base_dose*(stdy-count);

        end;

        else ex_pu2=exdose_sum;

run;

/* to check the the values are imputed and missing subjects for the period*/

%macro sa(inds=, outds=);

proc sort data=&inds. out=&inds.1(keep=usubjid flag_sa);by usubjid;run;

proc sort data=dm13 out=dm_sa(keep=usubjid);by usubjid;run;

data &outds.;

merge dm_sa(in=a) &inds.1(in=b);

by usubjid;

if a and not b then flag_miss=1;

run;

%mend;

%sa(inds=ex_pu2,outds=sm_pu2);

%sa(inds=ex_pu3,outds=sm_pu3);

%sa(inds=ex_pu4,outds=sm_pu4);

%sa(inds=ex_pu5,outds=sm_pu5);

data dm14a;

    merge dm13(in=a keep=usubjid armcd trt01an) ex_pu1 ex_pu2(drop=flag_sa)
ex_pu3(drop=flag_sa) ex_pu4(drop=flag_sa) ex_pu5(drop=flag_sa)

        dx_pu1 dx_pu2 dx_pu3 dx_pu4 dx_pu5 su_pu1 su_pu2 su_pu3 su_pu4 su_pu5;

    by usubjid;

```

```

if ex_pu1 ne . then
    do;
        if dx_pu1 eq . then
            dx_pu1=0;

        if dx_pu2 eq . then
            dx_pu2=0;

        if dx_pu3 eq . then
            dx_pu3=0;

        if dx_pu4 eq . then
            dx_pu4=0;

        if dx_pu5 eq . then
            dx_pu5=0;
    end;

if nmiss(ex_pu1,dx_pu1)=0 then
    do;
        if sum (ex_pu1,dx_pu1) ne 0 then
            do;
                ex_pu1a=(dx_pu1/(ex_pu1+dx_pu1))*100;
            end;
    end;
end;

```

```
if nmiss(dx_pu2,dx_pu2)=0 then
    do;
        if sum (ex_pu2,dx_pu2) ne 0 then
            do;
                ex_pu2a=(dx_pu2/(ex_pu2+dx_pu2))*100;
            end;
        end;
    end;
```

```
if nmiss(dx_pu3,dx_pu3)=0 then
    do;
        if sum (ex_pu3,dx_pu3) ne 0 then
            do;
                ex_pu3a=(dx_pu3/(ex_pu3+dx_pu3))*100;
            end;
        end;
    end;
```

```
if nmiss(dx_pu4,dx_pu4)=0 then
    do;
        if sum (ex_pu4,dx_pu4) ne 0 then
            do;
                ex_pu4a=(dx_pu4/(ex_pu4+dx_pu4))*100;
            end;
        end;
    end;
```

```

if nmiss(dx_pu5,dx_pu5,su_pu5)=0 then
    do;
        if sum (ex_pu5,dx_pu5) ne 0 then
            do;
                ex_pu5a=((dx_pu5/(ex_pu5+dx_pu5))*100);
                ex_pu5a=(ex_pu5a);
            end;
        end;
    end;

if armcd="SMABST" then
    do;
        if su_pu1 ne . then sa_pu1=su_pu1/(svendy_190-6); /* 6>=sustdy<=visit190*/

        if su_pu2 ne . then sa_pu2=su_pu2/(svendy_130-6); /*Period 2 is >=day
6 to <=(SV.SVENDY when VISITNUM=130).*/

        if su_pu3 ne . then sa_pu3=su_pu3/(svendy_160-svendy_130);
/* Period 3 is >(SV.SVENDY when VISITNUM=130) to <=(SV.SVENDY when VISITNUM=160).*/

        if su_pu4 ne . then
            sa_pu4=su_pu4/(svendy_190-svendy_160);

        if su_pu5 ne . then
            sa_pu5=su_pu5/(svendy_190-7);
    end;
end;

```

```

format ex_pu1a ex_pu2a ex_pu3a ex_pu4a ex_pu5a sa_pu1 sa_pu2 sa_pu3 sa_pu4 sa_pu5 8.2;

run;

proc sort data=ex_p2 out=ex1ba;

    by usubjid;

    where (exstdy>=6 and exendy<=svendy_190) and exscat in ("PRODUCT USE DIARY -
ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;

proc sort data=ex1ba out=ex1ba_1(keep=usubjid) nodupkey;by usubjid ;where exdose>0; run;

data ex_p1 ex_pucat1(keep=usubjid exdose);

    set ex1ba;

    if exdose=-9 then

        exdose=0;

    else if exdose eq . then

        delete;

    stdy=svendy_190-6+1;

    if exdose>2 then

        output ex_pucat1;

    else output ex_p1;

run;

proc sort data=ex_pucat1 nodupkey;

    by usubjid;

run;

```

```

proc sql;

    create table a as select distinct usubjid,count(usubjid)as count,sum(exdose) as exdose_sum,
    avg(exdose) as avg_pucat ,stdy,(((calculated count)*100/stdy)as per

        from ex_p1 where usubjid not in(select distinct usubjid from ex_pucat1) group by
    usubjid,stdy;    /*avg_pucat is used for deriving the pucat*/

quit;

```

```

proc sort data=lb out=lb1a;

    by usubjid;

    where lbtestcd="CO";

run;

```

```

data lb_p2a;

    merge lb1a(in=a) sv130 sv160 sv190;

    by usubjid;

    if a;

    if svenidy_130 eq . then

        svenidy_130=31;

    if svenidy_160 eq . then

        svenidy_160=61;

    if svenidy_190 eq . then

```



```

        svenidy_190=91;

run;


proc sort data=lb_p2a out=lb_1a(keep=usubjid)nodupkey;

    by usubjid;

    where lbtestcd="CO" and (6<=lbdy<=svenidy_190) and lbstresn<=10;

run;


proc sort data=lb_p2a out=lb_1b(keep=usubjid)nodupkey;

    by usubjid;

    where lbtestcd="CO" and (6<=lbdy<=svenidy_190) and lbstresn>10;

run;

data lb_1;

merge lb_1a(in=a) lb_1b(in=b);

by usubjid;

if a and not b;

run;


options missing=" ";

data pu1a;

    merge dm14a(in=a ) lb_1(in=b) lb_1b(in=s) su_p5ths a(in=c keep=usubjid exdose_sum
avg_pucat) ex_pucat1(in=g) ex1ba_1(in=h) base;

    by usubjid;

    length pucat1 PUCAT1EX gpucat1 $40.;

```

```

if a;

if trt01an=4 then do;

    if nmiss(exdose_sum,dx_pu1,su_pu1)=0 then do;

        if sum (exdose_sum,dx_pu1) ne 0 then do;

            ex_pu1a=(dx_pu1/(exdose_sum+dx_pu1))*100;

            end;

        end;

        pucat1=put(ex_pu1a,pucat.);

        gpucat1=put(ex_pu1a,gpucat.);

        if pucat1 = " " then do;

            if su_pu1>0 and .<avg_su<0.5 and .<max<=2 then
pucat1="Predominantly Abstinent";

            else if su_pu1>0 then    pucat1="Not Abstinent";

            else pucat1="Missing";

            end;

            if gpucat1 = " " then do;

                if su_pu1>0 and .<avg_su<0.5 and .<max<=2 then
gpucat1="Predominantly Abstinent";

                else if su_pu1>0 then    gpucat1="Not Abstinent";

```

```

else gpucat1="Missing";

end;

end;

if trt01an=5 then      do;

                        if nmiss(dx_pu1,su_pu1)=0 then do;

if sum(dx_pu1,su_pu1)=0 and ex_pu1 ne . then pucat1="CC Only";

                        else if sum(dx_pu1,su_pu1)>0 and ex_pu1 ne . then

pucat1="CC Dual";

                        end;

if strip(pucat1) eq " " then do;

                        if .<avg_pucat<0.5 then do;

pucat1="Predominantly Abstinent";

gpucat1="Predominantly Abstinent";

                        end;

                        end;

if base_dose ne . and pucat1 eq " " then pucat1="CC Only";

if base_dose ne . and gpucat1 eq " " then gpucat1="CC";

```

```

        if gpucat1 eq " " then gpucat1=put(ex_pu1a,gpucat.);
    end;

if trt01an=3 then      do;

        if ( g or avg_pucat>0.5 ) then      do;

                pucat1="Not Abstinent";

                gpucat1="Not Abstinent";

        end;

if pucat1 eq " " then do;

        if b and ex_pu1<=0 and dx_pu1<=0 and su_pu1 <= 0 then pucat1="Abstinent";

        if pucat1 eq " " then do;

                if a and .<avg_pucat<0.5 then do;

                        pucat1="Predominantly Abstinent";

                end;

        end;

        end;

        end;

        if pucat1 eq " " then pucat1="Not Abstinent";

if gpucat1 eq " " then do;

        if b and ex_pu1<=0 and dx_pu1<=0  and su_pu1 <= 0 then gpucat1="Abstinent";

```

```

    if gpucat1 eq " " then do;
        if /*h and*/ a and .<avg_pucat<0.5 then do;
            gpucat1="Predominantly Abstinent";
        end;
    end;
end;

    if gpucat1 eq "" then gpucat1="Not Abstinent";

end;

if pucat1 eq "Primarily THS 2.2" then do;
    if ex_pu1a=100 and su_pu1 eq 0 then pucat1ex="Exclusively THS 2.2";
end;
else if pucat1 eq "Primarily CC" then do;
    if ex_pu1a=0 and su_pu1 eq 0 then
        pucat1ex="Exclusively CC";
end;

if pucat1 ne " " then
    pucat1n=input(put(pucat1,$mccpucatn.),best.);

if gpucat1 ne " " then

```

```
gpucat1n=input(put(gpucat1,$ccgpucat.),best.);
```

```
keep usubjid pucat1 pucat1n gpucat: pucat1ex;
```

```
run;
```

```
%macro gpucat (finout=,in_ab=, ex=, dx=,sa= ,in_lb= ,avg_bi=, in_ex= ,in_dx= ,in_su=,pucatex= ,in_expu= ,in_expuavg=, pucat= ,pucatn= ,gpucat=,gpucatn=,dx_pu= , ex_pu=, su_pu=,base=,nrtths=,nrt=);
```

```
data &finout.;
```

```
merge dm14a(in=a drop=&dx_pu. &su_pu. svenidy_*)&avg_bi.(in=bi) &in_ab.(in=s)  
&in_lb.(in=b) &in_ex.(in=c keep=usubjid ) &dx_pu.(in=e) &su_pu.(in=f) &in_expu.(in=g)  
&in_expuavg.(in=h keep=usubjid) &ex.(in=ex) &dx.(in=dx) &sa. &base. &nrtths(keep=usubjid max  
avg_su) &nrt(in=nrt keep=usubjid) ;
```

```
by usubjid;
```

```
length &pucat. &gpucat. $40.;
```

```
if a;
```

```
if trt01an=5 then do;
```

```
if nmiss(&dx_pu.,&su_pu.) ne 2 then do;
```

```
if sum(&dx_pu.,&su_pu.)=0 and &ex_pu. ne . then &pucat.="CC  
Only";
```

```
else if sum(&dx_pu.,&su_pu.)>0 and &ex_pu. ne . then  
&pucat.="CC Dual";
```

```
end;
```

```
if &pucat. = " " then do;
```

```
if base_dose>0 then &pucat.="CC Only";
```

```
end;
```

```
if &pucat. = " " then do;
```

```
if bi then do ;
```

```
&pucat.="Predominantly Abstinent";
```

```
end;
```

```
end;
```

```
&gpucat. =put(&ex_pu.,gpucat. );
```

```
if &gpucat. = " " then do;
```

```
if base_dose>0 then &gpucat.="CC";
```

```
end;
```

```
end;
```

```
if trt01an=4 then do;
```

```
&pucat.=put(&ex_pu.,pucat.);
```

```
&gpucat. =put(&ex_pu.,gpucat. );
```

```
if &pucat. = " " then do;
```

```
    if &su_pu.>0 and .<avg_su<0.5 and .<max<=2 then  
&pucat.="Predominantly Abstinent";
```

```
    else if &su_pu.>0 then  &pucat.="Not Abstinent";
```

```
    else if flag_miss=1 and base_dose>0 then &pucat.='Primarily CC' ;
```

```
    else if b and &pucat. eq " " then &pucat.="Abstinent";
```

```
end;
```

```
if &gpucat. = " " then do;
```

```
    if &su_pu.>0 and .<avg_su<0.5 and .<max<=2 then  
&gpucat.="Predominantly Abstinent";
```

```
    else if &su_pu.>0 then  &gpucat.="Not Abstinent";
```

```
    else if flag_miss=1 and base_dose>0 then &gpucat.='CC' ;
```

```
    else if b and &gpucat. eq " " then &gpucat.="Abstinent";
```

```
end;
```

```
end;
```

```
if trt01an=3 then      do;
```



```
if b and not (ex or dx or nrt) then do;
```

```
&pucat.="Abstinent";
```

```
&gpucat.="Abstinent";
```

```
end;
```

```
if &pucat. eq " " then do;
```

```
    if c then do ;
```

```
        &pucat.="Predominantly Abstinent";
```

```
        &gpucat.="Predominantly Abstinent";
```

```
    end;
```

```
    else do;
```

```
        &pucat.="Not Abstinent";
```

```
    end;
```

```
end;
```

```
if &gpucat. =" " then &gpucat.="Not Abstinent";
```

```
if flag_sa=1 or flag_miss=1 then do;
```

```
    &pucat.="Not Abstinent";
```

```
    &gpucat.="Not Abstinent";
```

```
end;
```

```
end;
```

```
if &pucat. =" " and b then do;
```

```

        &pucat.="Abstinent";

        &gpucat.="Abstinent";

    end;

if &pucat. eq "Primarily THS 2.2" then do;

    if &ex_pu.=100 and &in_su.=0 then

        &pucatex.="Exclusively THS 2.2";

    end;

    else if &pucat. eq "Primarily CC" then do;

        if (&ex_pu.= 0 and &in_su.=0) or flag_miss=1 then

            &pucatex.="Exclusively CC";

        end;

    end;

if &pucat. ne "" then

    &pucatn.=input(put(&pucat.,$mccpucatn.),best.);

    if &gpucat. ne " " then

        &gpucatn.=input(put(&gpucat.,$ccgpucatn.),best.);

keep usubjid &pucat.: &gpucat.: &pucatex.;

run;

```

```
%mend;
```

```
proc sort data=lb_p2a out=lb_3a(keep=usubjid) nodupkey;
```

```
    by usubjid;
```

```
    where lbtestcd="CO" and (svenidy_130<lbdy<=svenidy_160) and lbstresn>10;
```

```
run;
```

```
proc sort data=lb_p2a out=lb_3b(keep=usubjid) nodupkey;
```

```
    by usubjid;
```

```
    where lbtestcd="CO" and (svenidy_130<lbdy<=svenidy_160) and lbstresn<=10;
```

```
run;
```

```
data lb_3;
```

```
merge lb_3b(in=a) lb_3a(in=b);
```

```
if a and not b;
```

```
by usubjid;
```

```
run;
```

```
proc sort data=lb_p2a out=lb_2a(keep=usubjid) nodupkey;
```

```
    by usubjid;
```

```
    where lbtestcd="CO" and (6<=lbdy<=svenidy_130/*31*/) and lbstresn>10;
```

```
run;
```

```
proc sort data=lb_p2a out=lb_2b(keep=usubjid) nodupkey;
```

```
    by usubjid;
```

```
    where lbtestcd="CO" and (6<=lbdy<=svenidy_130/*31*/) and lbstresn<=10;
```

```
run;
```

```

data lb_2;

merge lb_2b(in=a) lb_2a(in=b);

if a and not b;

by usubjid;

run;


proc sort data=lb_p2a out=lb_4a(keep=usubjid) nodupkey;

    by usubjid;

    where lbtestcd="CO" and (svendy_160/*61*/<lbdy<=svendy_190/*91*/) and lbstresn>10;

run;

proc sort data=lb_p2a out=lb_4b(keep=usubjid) nodupkey;

    by usubjid;

    where lbtestcd="CO" and (svendy_160/*61*/<lbdy<=svendy_190/*91*/) and lbstresn<=10;

run;


data lb_4;

merge lb_4b(in=a) lb_4a(in=b);

if a and not b;

by usubjid;

run;


proc sort data=lb_p2a out=lb_5b(keep=usubjid) nodupkey;

    by usubjid;

    where lbtestcd="CO" and (6<=lbdy<=svendy_190/*91*/) and lbstresn>10;

run;

```

```

proc sort data=lb_p2a out=lb_5a(keep=usubjid) nodupkey;

    by usubjid;

    where lbtestcd="CO" and (6<=lbdy<=svenidy_190/*91*/ ) and lbstresn<=10;

run;

data lb_5;

merge lb_5b(in=b) lb_5a(in=a);

if a and not b;

by usubjid;

run;

```

```

proc sort data=ex_p2 out=ex_cp5 (keep=usubjid) nodupkey;

    by usubjid;

    where (exstdy>=6 and exendy<=svenidy_190) and exdose>0 and exscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER");

run;

```

```

proc sort data=dx_p2 out=dx_cp5(keep=usubjid ) nodupkey;

    by usubjid;

    where (6<=dxstdy and dxendy<=svenidy_190) and dxscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and dxdose>0;

run;

```

```

%gpucat (finout=pu2,in_ab=lb_2a,ex=ex_cp2, dx=dx_cp2,sa=sm_pu2,avg_bi=pu2_bi, in_lb=lb_2 ,
in_ex=ex1b3,in_dx=dx_pu2 ,pucatex=pucat2ex,in_su=su_pu2, in_expu=ex_pucat2
,in_expuavg=expucat2_avg, pucat=pucat2
,pucatl=pu2n,gpucat=gpucat2,gpucatl=gpucat2n,dx_pu=dx_pu2 , ex_pu=ex_pu2a,
su_pu=su_pu2,base=base,nrtths=su_p2ths,nrt=su_p2thsnrt);

```

```
%gpucat (finout=pu3,in_ab=lb_3a,ex=ex_cp3, dx=dx_cp3,sa=sm_pu3, avg_bi=pu3_bi, in_lb=lb_3 ,
in_ex=ex_c33 ,in_dx=dx_pu3 ,in_su=su_pu3,pucatex=pucat3ex, in_expu=ex_pucat3
,in_expuavg=expucat3_avg, pucat=pucat3 ,pucatn=pucat3n,dx_pu=dx_pu3
,gpucat=gpucat3,gpucatn=gpucat3n, ex_pu=ex_pu3a,
su_pu=su_pu3,base=base,nrtths=su_p3ths,nrt=su_p3thsnrt);
```

```
%gpucat (finout=pu4,in_ab=lb_4a,ex=ex_cp4, dx=dx_cp4,sa=sm_pu4,avg_bi=pu4_bi, in_lb=lb_4 ,
in_ex=ex_c43 ,in_dx=dx_pu4 ,in_su=su_pu4,pucatex=pucat4ex, in_expu=ex_pucat4
,in_expuavg=expucat4_avg, pucat=pucat4 ,pucatn=pucat4n,dx_pu=dx_pu4
,gpucat=gpucat4,gpucatn=gpucat4n, ex_pu=ex_pu4a,
su_pu=su_pu4,base=base,nrtths=su_p4ths,nrt=su_p4thsnrt);
```

```
%gpucat (finout=pu5,in_ab=lb_5b,ex=ex_cp5, dx=dx_cp5,sa=sm_pu5, avg_bi=pu5_bi, in_lb=lb_5 ,
in_ex=ex_c53 ,in_dx=dx_pu5 ,in_su=su_pu5,pucatex=pucat5ex, in_expu=ex_pucat5
,in_expuavg=expucat5_avg, pucat=pucat5 ,pucatn=pucat5n,
gpucat=gpucat5,gpucatn=gpucat5n,dx_pu=dx_pu5 , ex_pu=ex_pu5a,
su_pu=su_pu5,base=base,nrtths=su_p5ths,nrt=su_p5thsnrt);
```

```
data dm14;
```

```
merge dm13(in=a) pu1a pu2 pu3 pu4 pu5;
```

```
by usubjid;
```

```
if a;
```

```
run;
```

```
/* LVISDT LVISDTC LVISIT FROM SV DOMAIN*/
```

```
proc sort data=sv out=sv1;
```

```
by usubjid svendtc;
```

```
where epoch ne "FOLLOWUP";
```

```
run;
```

```

data lvis;

    set sv1;

    by usubjid;

    length lvisdt 8. lvisdtc $20. lvisit $40.;


    if last.usubjid;

    lvisdtc=strip(svendtc);

    lvisdt=input(svendtc,yyymmdd10.);

    lvisit=strip(visit);

    format lvisdt date9.;

    keep usubjid lvis;

run;


/* LVISDAY DTESTDAY ICFDAY TRTSDAY TRTEDAY */

data dm15;

    merge dm14 lvis;

    by usubjid;

    length lvisday dtestday icfday trtsday trteday 8.;


    if nmiss(trtsdt,lvisdt)=0 then

        lvisday=lvisdt-trtsdt+1;


    if nmiss(trtsdt,dtestdt)=0 then

        dtestday=dtestdt-trtsdt+1;

```

```

if nmiss(trtsdt,icfdt)=0 then
    icfday=icfdt-trtsdt+1;

if length(rfstdtc)>10 then
    rfstdt=scan(rfstdtc,1,"T");
else rfstdt=rfstdtc;

if rfstdt ne "" and trtedt ne . then
    trteday=trtedt-input(rfstdt,yyymmdd10.)+1;

if rfstdt ne "" and trtsdt ne . then
    trtsday=trtsdt- input(rfstdt,yyymmdd10.)+1;

run;

PROC SORT DATA=SDTM.SE(WHERE=(EPOCH="FOLLOWUP")) OUT=SE(KEEP=USUBJID SESTDTC SEENDTC
EPOCH);

    BY USUBJID;

RUN;

DATA SE1;

    SET SE;

    IF CMISS(SESTDTC,SEENDTC)=0 THEN

        SEDY=INPUT(SEENDTC,YYMMDD10.)-INPUT(SESTDTC,YYMMDD10.);

    KEEP USUBJID SEDY EPOCH;

RUN;

```



```

/* PRODPREF*/

data qs1;

set sdtm.qs;

where qstestcd="RANDPREF";

keep usubjid qsorres qstestcd;

run;

proc sort data=qs1; by usubjid; run;

DATA DM16;

    MERGE DM15(drop=epoch) SE1 qs1;

    BY USUBJID;

    length DISFUCAT $40.prodpref $15.;

    prodpref=strip(qsorres);

    IF ENRLFL="Y" OR EXFL="Y" THEN

        DO;

            IF SEDY LT 28 THEN

                DISFUCAT="Discontinued follow-up";

        END;

    ELSE IF TRTSDT NE . AND EPOCH="" THEN

        DISFUCAT="Discontinued follow-up";

    DROP RFSTDT EPOCH SEDY;

RUN;


data dm16a;

set dm16;

dsreas=substr(dsreas,1,1)||lowercase(substr(dsreas,2));

```

```

if dsreasp ne " " then dsreasp=substr(dsreasp,1,1) || lowercase(substr(dsreasp,2));

/*lvisit=substr(lvisit,1,1) || lowercase(substr(lvisit,2));*/

lvisit=propcase(lvisit);

run;


data vd;

set crf.vd_disch;

/*where folder="DISCHARGE_1";*/

length usubjid $24.;

usubjid=strip(project) || "-" || strip(sitenum) || "-" || strip(subject);

keep usubjid distim;

run;


proc sort data=vd; by usubjid distim ; run;


data vd;

set vd;

by usubjid distim;

if first.usubjid;

run;

data dm16b;

merge dm16a(in=a) vd(in=b);

by usubjid;

if a;          /* updated as per client comment As per PMI if SA arm subject is discontinued we should
not assign 10:00 to TRTEDTM we should assing the min time from VISit of Discharge folder */

if DISCCAT not in (" " ,"Completed") and trt01a="SA" and distim ne " " then do;

```

```
trtedtm=dhms(trtedt,input(scan(distim,1,"."),best.),input(scan(distim,2,"."),best.),0);  
trtetmf=" ";  
end;  
if armcd in("SCRNFAIL","NOTASSGN")  
then call missing(pucat1,pucat2,pucat3,pucat4,pucat5,pucat1n,pucat2n,pucat3n,pucat4n,pucat5n,  
gpucat1,gpucat2,gpucat3,gpucat4,gpucat5,gpucat1n,gpucat2n,gpucat3n,gpucat4n,gpucat5n);  
run;
```

```
data dm16c;  
set dm16b;
```

```
if DISCCAT="Discontinued before randomization" then do;  
pucat1="Missing";  
pucat1n=99;  
gpucat1="Missing";  
gpucat1n=99;  
end;  
if DISCCAT eq "Discontinued Period 1 with randomized product use" then do;  
pucat1="Missing";pucat2="Missing";pucat3="Missing";pucat4="Missing";pucat5="Missing";  
pucat1n=99;pucat2n=99;pucat3n=99;pucat4n=99;pucat5n=99;  
gpucat1="Missing";gpucat2="Missing";gpucat3="Missing";gpucat4="Missing";gpucat5="Missing";  
gpucat1n=99;gpucat2n=99;gpucat3n=99;gpucat4n=99;gpucat5n=99;  
  
pucat2ex=" "; pucat3ex=" "; pucat4ex=" "; pucat5ex=" ";
```

```
end;

if disccat eq ("Discontinued Period 2") then do;

puc3="Missing";puc4="Missing";puc3n=99;puc4n=99;gpuc3="Missing";gpuc4="Missing";gpuc3n=99;gpuc4n=99;

puc5="Missing";puc5n=99;

gpuc5="Missing";gpuc5n=99;

puc3ex=" "; puc4ex=" "; puc5ex=" ";

end;
```

```
if disccat eq ("Discontinued Period 3") then do;

puc4="Missing";puc4n=99;gpuc4="Missing";gpuc4n=99;

puc5="Missing";puc5n=99;

gpuc5="Missing";gpuc5n=99;

puc4ex=" "; puc5ex=" ";

end;

run;
```

```
data adsl;

    set dm16c;

    format bmi exfl exnotrfl dsreasp ;

run;
```

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

```
data adsl;

set adsl;

label puc1="Product Use Cat.1- Ambulatory,Safety";
```

```
label pucat1n= "Product Use Cat.1â€“Ambulatory,Safety(N)";
```

```
run;
```

```
data adam.adsl(label="Subject Level Analysis Dataset");
```

```
set adsl;
```

```
run;
```

```
proc compare base=adam.adsl compare=qadam.qadsl listall;
```

```
run;
```

```
%m_logchk;
```