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/*=====
Covance Study ID   : COV-000000106343
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
=====
Modified by         :
Modification Date    :
Modification Description :

=====*/

OPTIONS VALIDVARNAME=UPCASE missing=" ";
PROC DATASETS LIBRARY=WORK KILL NOLIST;
RUN;

libname sdtm "/cvn/projects/prj/data/000000106343/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;
  ;
  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;
  ;
run;

data dm;
  set sdtm.dm(rename=(SUBJID=SUBJID_ SITEID=SITEID_ BRTHDTC=BRTHDTC_ ETHNIC=ETHNIC_));
  length subjdn sexn racen 8.  sexc $20. SUBJID $8. SITEID $3.  BRTHDTC $10. ETHNIC $22. ;
  format brthdt date9.;
  SUBJID=SUBJID_ ;
  SITEID=SITEID_ ;
  BRTHDTC=BRTHDTC_ ;
  ETHNIC=ETHNIC_;
  subjdn=input(scan(subjid,2,"-"),??best.);
  brthdt=input(brthdtc,ymmdd10.);

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if sex = 'M' then
do;
/*sex sexn*/
sex = 'Male';
sexn = 1;
end;
else if sex = 'F' then
do;
sex = '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
ethn = 1;
else if ethnic='NOT CAUCASIAN' then
ethn = 2;
else if ethnic = 'JAPANESE' then
ethn = 3;
else if ethnic = 'NOT JAPANESE' then
ethn = 4;
else if ethnic = 'HISPANIC OR LATINO' then
ethn = 5;
else if ethnic = 'NOT HISPANIC OR LATINO' then
ethn = 6;
/* else if (missing(ethnic) and armcd ne 'SCRNFAIL') or not missing(ethnic) then*/
/* put 'USER WARN' 'ING: Check Ethnicity for controlled terms: ' usubjid = ethn =;*/

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 /*rfstdt scrffl*/;
run;

/*randno*/
/*data rand;*/
/* set sdtm.suppdm(where=(qnam="DMRANDNO"));*/
/* length dmrando $10.;*/
/**/
/* if qnam="DMRANDNO" then*/
/* dmrando=strip(qval);*/
/* keep usubjid dmrando;*/
/*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;

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/*proc sort data=rand;*/
/* by usubjid;*/
/*run;*/

data dm1;
merge dm(in=a) suppdm_(in=b rename=(dmrandno=dmrandno_ raceoth=raceoth_));
by usubjid;
length dmrandno $10. raceoth $200.;
dmrandno=strip(dmrandno_);
raceoth=strip(raceoth_);
drop dmrandno_ raceoth_;
run;

/* VS data*/
data height;
set sdtm.vs(where=(vstestcd in("HEIGHT")));

if vstestcd="HEIGHT" and vsbfl 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 vsbfl="Y")) out=weight1a(keep=usubjid vsstresn rename=(vsstresn=weightbl));
by usubjid vsdte;
run;

proc sort data=height;
by usubjid;
run;

data vs;
merge height weight1a;
by usubjid;
format BMI 8.1;
length bmigr1 $40. bmigr1n 8.;
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;
/* else if not missing(bmi) then*/
/* put 'USER WARN' 'ING BMI unclassified: ' usubjid= bmi=;*/
run;

*****;
* add to DM;
*****;
data dm2;
merge DM1(in = a) vs(in = b);
by usubjid;

/* if (a and not b) and armcd ne 'SCRNFAIL' then*/
/* put 'USER WARN' 'ING baseline weight, height and BMI not available: ' usubjid= weightbl= height= bmi=;*/
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;

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*****;
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;

/* if (a and not b) and armcd ne 'SCRNFAIL' then*/
/* put 'USER WARN' 'ING baseline daily cigarette classification not available: ' 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 = ((fatestd='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;
/* else put 'USER WARN' 'ING unable to classify nicotine yield at baseline consumption: ' usubjid= nicobl=;*/
output;

* only keep nicotine yield information;
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 = (fatestd = 'TYIELD' and epoch = 'ADMI'));
  length tarbl targr1n 8. targr1 $20.;
  tarbl = fastresn;

if tarbl ne . and 1 le FLOOR(tarbl) le 5 then
  do;

    targr1 = '1-5 mg';
    targr1n = 1;
  end;
else if tarbl ne . and 6 le FLOOR(tarbl) le 8 then

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do;

    targr1 = '6-8 mg';
    targr1n = 2;
end;
else if tarbl ne . and 9 le FLOOR(tarbl) le 10 then
do;

    targr1 = '9-10 mg';
    targr1n = 3;
end;
else if tarbl ne . and tarbl gt 10 then
do;
    targr1 = '>10 mg';
    targr1n = 4;
end;
/* else put 'USER WARN' 'ING unable to classify tar yield at baseline: ' usubjid= tarbl=;*/
output;

* only keep tar yield information;
run;

/* Bring in baseline CO level data */
data co(keep=usubjid cobl);
set sdtm.su(where=(sutrtr='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;
/**/
/* if armcd ne 'SCRNFAIL' then*/
/* do;*/
/* if (a and not b) then*/
/* put 'USER WARN' 'ING baseline nicotine yield classification not available: ' usubjid=;*/
/**/
/* if (a and not c) then*/
/* put 'USER WARN' 'ING baseline tar yield classification not available: ' usubjid=;*/
/**/
/* if(a and not d) then*/
/* put "USER WARN" "ING baseline CO classification not available: " usubjid=;*/
/* end;*/
run;

data perf;
set sdtm.fa;
where fatestcd ="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;

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/* 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;
weightb1=WEIGHT_pt;
bmi=bmi_pt ;
bmigr1=bmigr1_pt;

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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 enr1fl="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'),TIM
E5.)),0);
  else if length(dxstdtc_)=10 then
    dtestdtm=dhms(input(dxstdtc_,ymmdd10.),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;

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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 in('PRODUCT USE CONFINEMENT','PRODUCT USE AMBULATORY')) out=ex_epoch(keep=usubjid epoch) nodupkey;
by usubjid; run;

proc sort data=dx(where=(epoch in('PRODUCT USE CONFINEMENT','PRODUCT USE AMBULATORY')) 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;
  *if length(exstdtc)=10 then exstdtc=strip(exstdtc) || 'T10:00';
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;
/* if exdx and none then*/
/* put 'USER WARN' 'ING: check subject treatment/exposure dates as in both SA and exposed: ' usubjid =;*/
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 do; trtsdtm=dhms(input(exstdtc,yyymmdd10.),0,0,0);
  trtstmf="H";
  end;
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;

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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*/

/* 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;
/* keep usubjid exstdtc exendtc exstdy excat visit epoch;*/
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;

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    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 suplds;
set sdtm.suplds;
dsseq=input(idvarval,??best.);
where qnam="OTHER";
keep usubjid dsseq qval;
run;

proc sort data=ds1;
by usubjid dsseq;
run;

proc sort data=suplds;
by usubjid dsseq;
run;

data ds;
merge ds1(in=a) suplds;
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);

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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;

/* if exdx and none then*/
/* put 'USER WARN' 'ING: check subject treatment/exposure dates as in both SA and exposed: ' usubjid =;*/
drop exendtc_ /*EXENDTC_NONDAY90*/;
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'),TIME
5.)),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;

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 randf1="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 randf1 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 rand
dt 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,ymmdd10.);
    output icf_t;
  end;

  if dsterm eq "INFORMED CONSENT FOR BIOMARKERS" then
  do;
    ICF02DTC=dsstdtc;
    ICF02DT=input(dsstdtc,ymmdd10.);
    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'),YMMDD10.),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,ymmdd10.),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;
*where dsterm ne " ";
run;

data comp_1(keep=usubjid dsstdtc);
set comp;
by usubjid;
if last.usubjid;
run;
data comp_2(keep=dsterm usubjid dsdecod);
set comp(where=(dsterm ne " "));
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_1 dsreasp comp_2;
by usubjid;
length complf1 fupfl $2. dsreas $147.;
format discdt date9.;

if a;

if dsdecod eq "COMPLETED" then
complf1="Y";
else complf1="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 strip(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 VIOLATION
S" ) then
dsreas=strip(dsterm);
run;

/*SV DATES-DISCCAT*/
data sv;
set sdtm.sv;
run;

proc sort data=sv out=sv_dis(keep=usubjid visitnum) nodupkey;
by usubjid;
where visitnum in (130,160,191);

```

```

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=130)) out=sv131(keep=usubjid svendy visitnum rename=(svendy=svstdy_131 visitnum=visit_131));
  by usubjid;
run;

proc sort data=sv(where=(visitnum=160)) out=sv161(keep=usubjid svendy visitnum rename=(svendy=svstdy_161 visitnum=visit_161));
  by usubjid;
run;

proc sort data=sv(where=(visitnum=191)) out=sv191(keep=usubjid svendy visitnum rename=(svendy=svstdy_191 visitnum=visit_191));
  by usubjid;
run;

* lab data for Biomarkers;
proc sort data = sdtm.lb(where = (lbcate 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;

data non;
  set sdtm.xp(keep=usubjid) sdtm.qs(keep=usubjid) sdtm.fa(keep=usubjid);
  flag=1;
run;

proc sort data=non nodupkey;
  by usubjid;
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 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;

proc sort data=sdtm.dx out=dx_dis(keep=usubjid) nodupkey ;
  where dxscat="PRODUCT USE DIARY - ELECTRONIC";
  by usubjid;
run;

proc sort data=sdtm.ex out=ex_dis(keep=usubjid) nodupkey ;
  where exscat="PRODUCT USE DIARY - ELECTRONIC";
  by usubjid;
run;

proc sort data=sdtm.su out=su_dis(keep=usubjid) nodupkey ;
  where suscat="PRODUCT USE DIARY - ELECTRONIC";
  by usubjid;

```

```

run;

proc sort data=sdtm.dx out=dx_dis1(keep=usubjid dxstdy) ;
where dxscat="PRODUCT USE DIARY - ELECTRONIC";
by usubjid;
run;

proc sort data=sdtm.ex out=ex_dis1(keep=usubjid exstdy) ;
where exscat="PRODUCT USE DIARY - ELECTRONIC";
by usubjid;
run;

proc sort data=sdtm.su out=su_dis1(keep=usubjid sustdy) ;
where suscat="PRODUCT USE DIARY - ELECTRONIC";
by usubjid;
run;

proc sort data=sv(where=(visitnum=130)) out=sv130(keep=usubjid svenidy visitnum rename=(svenidy=svenidy_130 visitnum=visit_131));
by usubjid;
run;

proc sort data=sv(where=(visitnum=160)) out=sv160(keep=usubjid svenidy visitnum rename=(svenidy=svenidy_160 visitnum=visit_161));
by usubjid;
run;

data dx_30 dx_60;
merge dx_dis1(in=a) sv130 sv160;
by usubjid;
if a;
if svenidy_130 =. then svenidy_130=31;
if svenidy_160= . then svenidy_160=61;
if dxstdy > svenidy_130 then output dx_30;
if dxstdy> svenidy_160 then output dx_60;
run;

data ex_30 ex_60;
merge ex_dis1(in=a) sv130 sv160;
by usubjid;
if a;
if svenidy_130 =. then svenidy_130=31;
if svenidy_160= . then svenidy_160=61;
if exstdy > svenidy_130 then output ex_30;
if exstdy> svenidy_160 then output ex_60;
run;

data su_30 su_60;
merge su_dis1(in=a) sv130 sv160;
by usubjid;
if a;
if svenidy_130 =. then svenidy_130=31;
if svenidy_160= . then svenidy_160=61;
if sustdy > svenidy_130 then output su_30;
if sustdy> svenidy_160 then output su_60;
run;

proc sort data=dx_30(keep=usubjid) nodupkey ;
by usubjid;
run;
proc sort data=dx_60(keep=usubjid) nodupkey;
by usubjid;
run;
proc sort data=ex_30(keep=usubjid) nodupkey ;
by usubjid;
run;
proc sort data=ex_60(keep=usubjid) nodupkey;
by usubjid;
run;
proc sort data=su_30(keep=usubjid) nodupkey ;
by usubjid;
run;
proc sort data=su_60(keep=usubjid) nodupkey;
by usubjid;
run;

```

```

data dm9a;
merge dm9(in=a) dx_30(in=b) dx_60(in=c) ex_30(in=d) ex_60(in=e) su_30(in=f) su_60(in=g) ;
if a;
by usubjid;
if b then flag_dx30=1;
if c then flag_dx60=1;
if d then flag_ex30=1;
if e then flag_ex60=1;
if f then flag_su30=1;
if g then flag_su60=1;
run;

proc sort data=sdtm.sv out=sv_ls;
by usubjid visitnum;
where index(visit,"UNSCHEDULED")=0;
run;

data sv_ls1;
set sv_ls;
by usubjid visitnum;
if last.usubjid;
keep usubjid svenidy;
rename svenidy=svenidy_ls;
run;

data dm10;
merge dm9a(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) sv_dis(in=h) ex_dis(in=i) d
x_dis(in=j) su_dis(in=k) sv_ls1 ;
by usubjid;

if a;
/* if svenidy_ls <= svstdy_161 and flag_ex60 = . and flag_dx60= . and flag_su60 = . then flag=1;*/
/* keep usubjid flag;*/
if h then flag_dis=1;
if i then flag_ex=1;
if j then flag_dx=1;
if k then flag_su=1;
length disccat $52. fasfl /*saffl*/ safbfl safaf1 /*fsaffl*/ $2. fasreas $200. /*safreas fsafreas*/safbrea $50. safarea $65.;
if svstdy_131 eq . then svstdy_131=31;
if svstdy_161 eq . then svstdy_161=61;
/* safbfl safaf1 safreas fsafreas*/
if f and icfdtm ne . then safbfl="Y"; else safbfl="N";
if randfl="Y" and flag1=1 then safaf1="Y";else safaf1="N";
if safbfl="N" then do;
if icfdtm eq . then safbrea="Did not give informed consent";
else if not f then safbrea= "Not exposed to THS 2.2";
end;

if safbfl="N" then safarea=safbrea;
else if safaf1="N" then safarea="Subjects did not have valid safety assessment post-randomization";

/*DISCCAT*/
if enr1fl="Y" then do;
if randfl="N" then
disccat="Discontinued before randomization";
else if dsdecod="COMPLETED" then disccat="Completed";
else if /*visit_191 eq .*/ flag_dis =. then do;
if trtsdt eq . then disccat="Discontinued Period 1 without randomized product use";
else if nmiss(flag_ex ,flag_dx,flag_su)=3 then disccat="Discontinued Period 1 with randomized product use";
end;

if dsreas ne " " and disccat eq " " then do;
if svenidy_ls <= svstdy_131 and nmiss(flag_ex30,flag_dx30,flag_su30)=3 then disccat="Discontinued Period 2";
else if svenidy_ls <= svstdy_161 and flag_ex60 = . and flag_dx60= . and flag_su60 = . then disccat="Discontinued Per
iod 3";
else disccat="Discontinued Period 4";
end;
/* else if visit_131 eq . and visit_161 eq . then*/
/* disccat ="Discontinued Period 2";*/
/* else if visit_161 ne . then*/
/* disccat="Discontinued Period 4";*/
/* else if visit_131 ne . then*/
/* disccat="Discontinued Period 3";*/
end;

if b then

```



```

do;
  if randfl="Y" then
    do;
      if (armcd eq "THS 2.2M" and epoch_exdx in("PRODUCT USE CONFINEMENT","PRODUCT USE AMBULATORY") and trtsdtm ne . ) or (armcd eq "
MCC" and epoch_exdx in("PRODUCT USE CONFINEMENT","PRODUCT USE AMBULATORY") 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 fasfl="Y" and siteid="TOK" then*/
/*  saffl="Y";*/
/* else saffl="N";*/
/**/
/*if d and  randfl eq "N" and icfdt ne .  then saffl="Y"; */
/* else if randfl="Y" and e then*/
/*  saffl="Y";*/
/* else saffl="N";*/
/**/
/* if siteid="SEI" then*/
/*  saffl="N";*/
/**/
/**/
/* /*SAFREAS*/ */
/* if saffl="N" then*/
/*  do;*/
/*    if siteid="SEI" then*/
/*      safreas="Site terminated due to ICH/GCP non-compliance";*/
/*    else if not missing(icfdt) and not c then*/
/*      safreas="No exposure to THS 2.2";*/
/*    else if missing(icfdt) then*/
/*      safreas="No informed consent";*/
/*    else if not e /*and siteid ne "SEI" */then*/
/*      safreas="Did not have any valid safety post-randomization assessments";*/
/*    else safreas="Reason for exclusion from the Analysis Population";*/
/*  end;*/;

/* FSAFFL*/
/* if d and  randfl eq "N" and icfdt ne .  then fsaffl="Y"; /*else fsaffl="N";*/ */
/* else if randfl="Y" and b then*/
/*  fsaffl="Y";*/
/* else fsaffl="N";*/
/**/
/* if siteid="SEI" then*/
/*  fsaffl="N";*/
/**/
/* /*FSAFREAS*/ */
/* if fsaffl="N" then do;*/
/*  if not missing(icfdt) and not c then*/

```

```

/*      fsafreas="No exposure to THS 2.2";*/
/*      else if missing(icfddt) then*/
/*      fsafreas="No informed consent";*/
/*      else fsafreas="Reason for exclusion from the Analysis Population";*/
/*      end;*/;

drop visit_106 svstdy_106 svstdy_131 visit_131 svstdy_161 visit_161 svstdy_191 visit_191 fasreas1-fasreas5 DXSTDTC_P flag;;
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 sucat 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=lb1e(keep=usubjid) nodupkey;
  by usubjid;
  where lbtestcd="C0" and (2<=lbdy<=6) and lbstresn <= 10;
run;

proc sort data=lb out=lb2e(keep=usubjid) nodupkey;
by usubjid;
  where lbtestcd="C0" and (2<=lbdy<=6) and lbstresn > 10;
run;

data lb1;
merge lb1e(in=a) lb2e(in=b);
  by usubjid;
  if a and not b;
run;

proc sort data=sv(where=(visitnum=130)) out=sv130(keep=usubjid svendy visitnum rename=(svendy=svendy_130 visitnum=visit_130));
  by usubjid;
run;

proc sort data=sv(where=(visitnum=160)) out=sv160(keep=usubjid svendy visitnum rename=(svendy=svendy_160 visitnum=visit_160));
  by usubjid;
run;

proc sort data=sv(where=(visitnum=190)) out=sv190(keep=usubjid svendy visitnum rename=(svendy=svendy_190 visitnum=visit_190));
  by usubjid;
run;

proc sort data=ex;
  by usubjid;
run;

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```

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 svenidy_130 eq . then
    svenidy_130=31;

  if svenidy_160 eq . then
    svenidy_160=61;

  if svenidy_190 eq . then
    svenidy_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;

proc sort data=ex_p2 out=ex2_sa(keep=usubjid) nodupkey;
  by usubjid;
  where (exstdy>=6 and exendy<=svenidy_130) and exscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and exdose>=0
  ;
run;

data ex1b1 ex_pucat2(keep=usubjid );
  set ex1b;

  if exdose=-9 then
    exdose=0;
  else if exdose=-1 then
    exdose=.;
  stdy=svenidy_130-6+1;

  /*else if exdose eq "" then delete;*/
  if exdose>2 then
    output ex_pucat2;
  else output ex1b1;
run;

proc sort data=ex_pucat2 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 p
er
  from ex1b1 where usubjid not in(select distinct usubjid from ex_pucat2 /*ex1b1 where exdose>2*/) group by usubjid,stdy ;      /*a
vg_pucat is used for deriving the pucat*/
quit;

data ex1b3 expucat2_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>svendy_130 and exendy<=svendy_160) and exscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER");
run;

/*to check the subject present in Period 3*/

proc sort data=ex_p2 out=ex3_sa(keep=usubjid)nodupkey;
    by usubjid;
    where (exstdy>svendy_130 and exendy<=svendy_160) and exscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and e
xdose>=0;
run;
data ex_c31 ex_pucat3(keep=usubjid);
    set ex_c3;

if exdose=-9 then
    exdose=0;
else if exdose=-1 then
    exdose=.;
stdy=svendy_160-svendy_130+1;

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

proc sort data=ex_pucat3 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 pe
r
    from ex_c31 where usubjid not in(select distinct usubjid from ex_pucat3 /*ex_c31 where exdose>2*/) group by usubjid,stdy;
quit;

data ex_c32 expucat3_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);
end;

if .<avg_bi<0.5 then output pu3_bi;
/*if exdose_sum=. then exdose_sum=0;*/
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;
/*to check the subject present in Period 4*/

proc sort data=ex_p2 out=ex4_sa(keep=usubjid) nodupkey;
  by usubjid;
  where (exstdy>svendy_160 and exendy<=svendy_190) and exscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and e
xdose>=0;
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;

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 /*ex_c41 where exdose>2*/)group by usubjid,stdy;
quit;

data ex_c42 expucat4_avg(keep=usubjid avg_) pu4_bi(keep=usubjid);
  merge z(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 pu4_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_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;

/*to check subject present in period 5*/
proc sort data=ex_p2 out=ex5_sa(keep=usubjid) nodupkey;
  by usubjid;
  where (exstdy>6 and exendy<=svendy_190) and exscat in ("PRODUCT USE DIARY - ELECTRONIC", "PRODUCT USE DIARY - PAPER") and exdose>=0;
run;

proc sort data=ex_p2 out=ex_c5;
  by usubjid;
  where (exstdy>6 and exendy<=svendy_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=svendy_190-6+1;

  if exdose>2 then
    output ex_pucat5;
  else output ex_c51;
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;
  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 pu5_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_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 cmpcp1f1 cmpcp2f1 cmpcp3f1 cmpcp4f1 cmpcovf1 $2.;

  if fasf1="Y" then
    do;
      if trt01p="THSm2.2" and not(b /*or d*/) then
        cmpcp1f1="Y";
    end;

```

```

else cmpcp1f1="N";

if trt01p="mCC" then
  cmpcp1f1="Y";

if trt01p="SA" then do;
  if not (c or b /*or d*/) and e then
    cmpcp1f1="Y";
  else cmpcp1f1="N";
end;
end;
else if fasf1="N" then
  cmpcp1f1="N";

if fasf1="Y" then
do;
  if trt01p in ("THSm2.2","SA") and f then
    cmpcp2f1="Y";
  else if trt01p="mCC" then
    cmpcp2f1="Y";
  else cmpcp2f1="N";
end;
else if fasf1="N" then
  cmpcp2f1="N";

if fasf1="Y" then
do;
  if trt01p in ("THSm2.2","SA") and g then
    cmpcp3f1="Y";
  else if trt01p="mCC" then
    cmpcp3f1="Y";
  else cmpcp3f1="N";
end;
else if fasf1="N" then
  cmpcp3f1="N";

if fasf1="Y" then
do;
  if trt01p in ("THSm2.2","SA") and h then
    cmpcp4f1="Y";
  else if trt01p="mCC" then
    cmpcp4f1="Y";
  else cmpcp4f1="N";
end;
else if fasf1="N" then
  cmpcp4f1="N";

  if DISCCAT = "Discontinued Period 1 with randomized product use" then do; /*updated as per spec1May2015*/
if trt01p in ("THSm2.2","SA") and base_dose>0 then cmpcp1f1="N";
cmpcp2f1="N";
cmpcp3f1="N";
cmpcp4f1="N";
end;

else if DISCCAT in( "Discontinued Period 2") then do;
cmpcp3f1="N";
cmpcp4f1="N";
end;

else if DISCCAT in("Discontinued Period 3"/*,"Discontinued Period 4"*/) then do;
cmpcp4f1="N";
end;

  if cmpcp1f1=cmpcp2f1=cmpcp3f1=cmpcp4f1="Y" then
    cmpcovf1="Y";
  else cmpcovf1="N";
run;

/*PPROT1FL*/
/*data dv;*/
/* set sdtm.dv;*/
/*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;

proc sort data=dv out=dv_pall(keep=usubjid dvcat rename=(dvcat=dvcat_pall)) nodupkey;
by usubjid;
where dvcat in ("MIS-RANDOMIZATION",/*'MIS-USE OF PRODUCT',*/"VIOLATION") ;
RUN;

proc sort data=dv out=dv_othall(keep=usubjid dvcat rename=(dvcat=dvcat_othall)) nodupkey;
by usubjid;
where dvcat in ("OTHER") and dvscat="ALL" ;
RUN;

proc sort data=dv out=dv_p1(keep=usubjid dvcat rename=(dvcat=dvcat_p1)) nodupkey;
by usubjid;
where dvcat in ("MIS-RANDOMIZATION",/*'MIS-USE OF PRODUCT',*/"VIOLATION","DURATION OF 24 HOUR COLLECTION","OTHER") and (1<=visitdy<=6);
RUN;

proc sort data=dv out=dv_p2(keep=usubjid dvcat rename=(dvcat=dvcat_p2)) nodupkey;
by usubjid;
where dvcat in ("MIS-RANDOMIZATION",/*'MIS-USE OF PRODUCT',*/"VIOLATION","DURATION OF 24 HOUR COLLECTION","OTHER") and (6<=visitdy<=svenidy_130);
RUN;

proc sort data=dv out=dv_p3(keep=usubjid dvcat rename=(dvcat=dvcat_p3)) nodupkey;
by usubjid;
where dvcat in ("MIS-RANDOMIZATION",/*'MIS-USE OF PRODUCT',*/"VIOLATION","DURATION OF 24 HOUR COLLECTION","OTHER") and (svenidy_130<visitdy<=svenidy_160);
RUN;

proc sort data=dv out=dv_p4(keep=usubjid dvcat rename=(dvcat=dvcat_p4)) nodupkey;
by usubjid;
where dvcat in ("MIS-RANDOMIZATION",/*'MIS-USE OF PRODUCT',*/"VIOLATION","DURATION OF 24 HOUR COLLECTION","OTHER") and (svenidy_160<visitdy<=svenidy_190);
RUN;

data dm12;
merge dm11(in=a) dv_p1(in=b) dv_p2(in=c) dv_p3(in=d) dv_p4(in=e) dv_pall(in=f) dv_othall(in=g);;
by usubjid;

if a;
length pprot1f1 pprot2f1 pprot3f1 pprot4f1 $2. ppreas1-ppreas4 $200.
ppreas1a ppreas2a ppreas3a ppreas4a $200. ppreas1b ppreas2b ppreas3b ppreas4b $200. ppreas1c ppreas2c ppreas3c ppreas4c $200. ;

if fasf1="Y" and cmpcp1f1="Y" and not (b or f or g)then
    pprot1f1="Y";
else pprot1f1="N";

if fasf1="Y" and cmpcp2f1="Y" and not (c or f or g) then
    pprot2f1="Y";
else pprot2f1="N";

if fasf1="Y" and cmpcp3f1="Y" and not (d or f or g)then
    pprot3f1="Y";
else pprot3f1="N";

if fasf1="Y" and cmpcp4f1="Y" and not (e or f or g) then

```



```

    pprot4f1="Y";
else pprot4f1="N";

if fasf1="N" then do;
    ppreas1="Not in FAS";
    ppreas2="Not in FAS";
    ppreas3="Not in FAS";
    ppreas4="Not in FAS";
end;
else if fasf1="Y" then do;
    if upcase(dvcat_p1)="PRODUCT COMPLIANCE" or cmpcp1f1="N" then
        ppreas1b="Has major protocol deviations not compliant";
    if /*dvcat_p1 ne " " */(b or f) then
        ppreas1c="Has other major protocol deviations impacting evaluability";

    if upcase(dvcat_p2)="PRODUCT COMPLIANCE" or cmpcp2f1="N" then
        ppreas2b="Has major protocol deviations not compliant";
    if /*dvcat_p2 ne " " */(c or f) then
        ppreas2c="Has other major protocol deviations impacting evaluability";

    if upcase(dvcat_p3)="PRODUCT COMPLIANCE" or cmpcp3f1="N" then
        ppreas3b="Has major protocol deviations not compliant";
    if /*dvcat_p3 ne " " */(d or f) then
        ppreas3c="Has other major protocol deviations impacting evaluability";

    if upcase(dvcat_p4)="PRODUCT COMPLIANCE" or CMPCP4FL="N" then
        ppreas4b="Has major protocol deviations not compliant";
    if /*dvcat_p4 ne " " */(e or f) then
        ppreas4c="Has other major protocol deviations impacting evaluability";

    if cmiss(ppreas1b,ppreas1c)=0 then ppreas1=strip(ppreas1b)||"||"||strip(ppreas1c);
    else if ppreas1b ne " " and ppreas1c eq " " then ppreas1=strip(ppreas1b);
    else if ppreas1b eq " " and ppreas1c ne " " then ppreas1=strip(ppreas1c);

    if cmiss(ppreas2b,ppreas2c)=0 then ppreas2=strip(ppreas2b)||"||"||strip(ppreas2c);
    else if ppreas2b ne " " and ppreas2c eq " " then ppreas2=strip(ppreas2b);
    else if ppreas2b eq " " and ppreas2c ne " " then ppreas2=strip(ppreas2c);

    if cmiss(ppreas3b,ppreas3c)=0 then ppreas3=strip(ppreas3b)||"||"||strip(ppreas3c);
    else if ppreas3b ne " " and ppreas3c eq " " then ppreas3=strip(ppreas3b);
    else if ppreas3b eq " " and ppreas3c ne " " then ppreas3=strip(ppreas3c);

    if cmiss(ppreas4b,ppreas4c)=0 then ppreas4=strip(ppreas4b)||"||"||strip(ppreas4c);
    else if ppreas4b ne " " and ppreas4c eq " " then ppreas4=strip(ppreas4b);
    else if ppreas4b eq " " and ppreas4c ne " " then ppreas4=strip(ppreas4c);

end;

/*comment above and uncomment below after checking with Yankui*/
if disccat eq "Discontinued Period 1 with randomized product use" and pprot2f1="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 pprot3f1="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 pprot4f1="N" then ppreas4="Discontinued in previous period";

if DVCAT_OTHALL="OTHER" then ppreas1a="Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization";
else ppreas1a=ppreas1;
if DVCAT_OTHALL="OTHER" then
    ppreas2a=strip(ppreas2)||"||"||"Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization";
else ppreas2a=ppreas2;
if DVCAT_OTHALL="OTHER" and ppreas3 not in("Discontinued in previous period","Not in FAS")
then ppreas3a=strip(ppreas3)||"||"||"Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization";
else ppreas3a=ppreas3;
if DVCAT_OTHALL="OTHER" and ppreas4 not in("Discontinued in previous period","Not in FAS")
then ppreas4a=strip(ppreas4)||"||"||"Access to medical records were granted for SDV and data entry after withdrawal of PHI authorization";
else ppreas4a=ppreas4;

drop dvcat_p;
drop ppreas1-ppreas4;

```

```
rename ppreas1a=ppreas1 ppreas2a=ppreas2 ppreas3a=ppreas3 ppreas4a=ppreas4;
drop ppreas1b ppreas2b ppreas3b ppreas4b ppreas1c ppreas2c ppreas3c ppreas4c ;
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 svendy_130 eq . then
  svendy_130=31;
```

```
if svendy_160 eq . then
  svendy_160=61;
```

```
if svendy_190 eq . then
  svendy_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 svendy_130 eq . then
  svendy_130=31;
```

```
if svendy_160 eq . then
  svendy_160=61;
```

```
if svendy_190 eq . then
  svendy_190=91;
```

```
run;
```

```
proc sort data=lb out=lb1;
  by usubjid;
  where lbtestcd="C0" and lbstresn<=10;
run;
```

```
proc sort data=lb out=lb1b;
  by usubjid;
  where lbtestcd="C0" and lbstresn>10;
run;
```

```
data lb_co10;
merge lb1b(in=a) sv130 sv160 sv190;
by usubjid;
```

```
if a;
```

```
if svendy_130 eq . then
  svendy_130=31;
```

```
if svendy_160 eq . then
  svendy_160=61;
```

```
if svendy_190 eq . then
  svendy_190=91;
```

```
run;
```

```
data lb_p2;
merge lb1(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=ex_p2 out=ex_cp2(keep=usubjid ) nodupkey;
    by usubjid;
    where (exstdy>=6 and exendy<=svenidy_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>svenidy_130 and exendy<=svenidy_160) and exscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and exdose>0;
run;

proc sort data=ex_p2 out=ex_cp4 (keep=usubjid) nodupkey;
    by usubjid;
    where (exstdy>svenidy_160 and exendy<=svenidy_190) and exscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and exdose>0;
run;

proc sort data=dx_p2 out=dx_cp2(keep=usubjid ) nodupkey;
    by usubjid;
    where (6<=dxstdy and dxendy<=svenidy_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 (svenidy_130<dxstdy and dxendy<=svenidy_160) and dxscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and dxdose>0;
run;

proc sort data=dx_p2 out=dx_cp4 (keep=usubjid ) nodupkey;
    by usubjid;
    where (svenidy_160<dxstdy and dxendy<=svenidy_190) and dxscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and dxdose>0;
run;

proc sort data=su_p2 out=su_cp2(keep=usubjid ) nodupkey;
    by usubjid;
    where (6<=sustdy<=svenidy_130) and suscat 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 suscat 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_cp4 (keep=usubjid) nodupkey;
    by usubjid;
    where (svenidy_160<sustdy<=svenidy_190) and suscat ne "NRT_USE" and suscat in ("PRODUCT USE DIARY - PAPER","PRODUCT USE DIARY - ELECTRONIC") and sudose>0;
run;

proc sort data=lb_p2 out=lb_cp2a(keep=usubjid ) nodupkey;
    by usubjid;
    where (6<lbdy<=svenidy_130);
run;

proc sort data=lb_co10 out=lb_cp2b(keep=usubjid ) nodupkey;
    by usubjid;
    where (6<lbdy<=svenidy_130);
run;

```

```

data lb_cp2;
merge lb_cp2a(in=a) lb_cp2b(in=b);
by usubjid;
if a and not b;
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_co10 out=lb_cp3b(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 (svenidy_160<lbdy<=svenidy_190);
run;

data dm13a;
merge dm12(in=a keep=usubjid pprot2f1 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 comp2f1 $2.;

if PPR0T2FL="Y" then do;
if trt01p="THSm2.2" then do;
if N(flag_ex ,flag_su )=0 and flag_dx=1 then
comp2f1="Y";
end;

if trt01p="mCC" then do;
if N(flag_su,flag_dx)=0 then
comp2f1="Y";
end;

if trt01p="SA" then do;
if N(flag_dx ,flag_su,flag_ex )=0 and flag_lb eq 1 then
comp2f1="Y";
end;

if comp2f1^="Y" then
comp2f1="N";
end;
else if pprot2f1="N" then
comp2f1="N";
keep usubjid comp2f1;
run;

data dm13b;
merge dm12(in=a keep=usubjid pprot3f1 trt01p ) ex_cp3(in=b) dx_cp3(in=c) su_cp3(in=d) lb_cp3(in=e) lb_cp3b(in=f);
by usubjid;

if a;
length comp3f1 $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 f then flag_lb10=1;

if pprot3f1="Y" then
do;
  if trt01p="THSm2.2" then
do;
  if N(flag_ex ,flag_su )=0 and flag_dx=1 then
    comp3f1="Y";
  end;

  if trt01p="mCC" then
do;
  if N(flag_su,flag_dx)=0 then
    comp3f1="Y";
  end;

  if trt01p="SA" then
do;
  if N(flag_dx ,flag_su,flag_ex )=0 and flag_lb eq 1/* ((flag_lb eq 1 and flag_lb10= .) or (flag_lb =. and flag_lb10= .))*/ then
    comp3f1="Y";
  end;

  if comp3f1^="Y" then
    comp3f1="N";
end;
else if pprot3f1="N" then
  comp3f1="N";
keep usubjid comp3f1;
run;

data dm13c;
merge dm12(in=a keep=usubjid pprot4f1 trt01p ) ex_cp4(in=b) dx_cp4(in=c) su_cp4(in=d) lb_cp4(in=e);
by usubjid;

if a;
length comp4f1 $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 pprot4f1="Y" then
do;
  if trt01p="THSm2.2" then
do;
  if N(flag_ex ,flag_su )=0 and flag_dx=1 then
    comp4f1="Y";
  end;

  if trt01p="mCC" then
do;
  if N(flag_su,flag_dx)=0 then
    comp4f1="Y";
  end;

  if trt01p="SA" then
do;
  if N(flag_dx ,flag_su,flag_ex )=0 and flag_lb eq 1 then
    comp4f1="Y";
  end;

  if comp4f1^="Y" then
    comp4f1="N";
end;
else if pprot4f1="N" then

```

```

    comp4f1="N";
    keep usubjid comp4f1;
run;

data dm13;
merge dm12(in=a) dm13a dm13b dm13c;
by usubjid;
length comp1f1 compovf1 $2.;
comp1f1=pprot1f1;

if comp1f1=comp2f1=comp3f1=comp4f1="Y" then
    compovf1="Y";
else compovf1="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;
/* if dxdose=-9 then */
/* dxdose=0; */
/* else if dxdose=-1 then */
/* delete; */

run;

data su_p2;
set su_p2;
/**/
/* if sudose=-9 then */
/* sudose=0; */
/* else if sudose=-1 then */
/* delete; */

if sudostxt="-9" then sudose=0;
else if sudostxt="-1" then delete;
run;

proc sort data=su_p2 out=su_n1(keep=usubjid) nodupkey;
by usubjid;
where (sustdy>=6 and sustdy<=svenidy_190) and sudose>0 and suscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER")
and suscat ne "CAFFEINE";
run;
/*FOR PUCAT derivation of THS */
/*period 2*/
proc sort data=su_p2 out=su_n2;
by usubjid;
where (sustdy>=6 and sustdy<=svenidy_130) and sudose>0 and suscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER")
and suscat 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 (svenidy_130<sustdy<=svenidy_160) and sudose>0 and suscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") an
d suscat 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
d sucat 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 sucat
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
sucat 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 (svendy_130<sustdy<=svendy_160) 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_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 (svendy_160<sustdy<=svendy_190) and sudose>0 and suscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") and
d
  sucat 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_nonrt,

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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<=svendy_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 (svendy_130<dxstdy<=svendy_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 (svendy_160<dxstdy<=svendy_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<=svendy_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,svendy_190 from su_p2 where (6<=sustdy<=svendy_190) and suscat ne "NRT_U SE" and suscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") group by usubjid,svendy_190;
  create table su_pu2 as select usubjid,sum(sudose) as su_pu2,svendy_130 from su_p2 where (6<=sustdy<=svendy_130) and suscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") group by usubjid,svendy_130;
  create table su_pu3 as select usubjid,sum(sudose) as su_pu3,svendy_160 from su_p2 where (svendy_130<sustdy<=svendy_160) and suscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") group by usubjid,svendy_160;
  create table su_pu4 as select usubjid,sum(sudose) as su_pu4 from su_p2 where (svendy_160<sustdy<=svendy_190) and suscat 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<=svendy_190) and suscat in ("PRODUCT USE DIARY - ELECTRONIC","PRODUCT USE DIARY - PAPER") group by usubjid;
quit;

/**/
/* NEED TO UPDATE FROM HERE*/
%macro pucat(out1= ,svdy= , svendy= , 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.)+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);
    else if base_dose eq . then &ex_pu.=exdose_sum;
  end;
  else &ex_pu.=exdose_sum;
run;

%mend;

%macro pucat5(out1= ,svdy= , svendy= , 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");

```



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run;

data &out2.;
  set &out1.;
  stdy=(&svendy.-&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);
  else if base_dose eq . then &ex_pu.=exdose_sum;
end;
else &ex_pu.=exdose_sum;
run;

%mend;

%pucat(out1=ex_pu3a,svdy=svendy_130, svendy=svendy_160,out2=ex_pu3b,out3=ex_pu3c,ex_pu=ex_pu3,finout=ex_pu3);
%pucat(out1=ex_pu4a,svdy=svendy_160, svendy=svendy_190,out2=ex_pu4b,out3=ex_pu4c,ex_pu=ex_pu4,finout=ex_pu4);
%pucat5(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<=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;

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_pu3= . then ex_pu3=0;
if ex_pu5 =. then ex_pu5=0; /*updated because of the subject 1042*/
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/*,su_pu1*/) =0 then
do;
  if sum (ex_pu1,dx_pu1/*,su_pu1*/) ne 0 then
  do;
    ex_pu1a=(dx_pu1/(ex_pu1+dx_pu1/*+su_pu1*)) *100;
  end;
end;

if nmiss(dx_pu2,ex_pu2/*,su_pu2*/) =0 then
do;
  if sum (ex_pu2,dx_pu2/*,su_pu2*/) ne 0 then
  do;
    ex_pu2a=(dx_pu2/(ex_pu2+dx_pu2/*+su_pu2*)) *100;
  end;
end;

if nmiss(dx_pu3,ex_pu3/*,su_pu3*/) =0 then
do;
  if sum (ex_pu3,dx_pu3/*,su_pu3*/) ne 0 then
  do;
    ex_pu3a=(dx_pu3/(ex_pu3+dx_pu3/*+su_pu3*)) *100;
  end;
end;

if nmiss(dx_pu4,ex_pu4/*,su_pu4*/) =0 then
do;
  if sum (ex_pu4,dx_pu4/*,su_pu4*/) ne 0 then

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do;
  ex_pu4a=(dx_pu4/(ex_pu4+dx_pu4/*+su_pu4*/))*100;
end;
end;

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

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

/* keep usubjid armcd ex_pu1a ex_pu2a ex_pu3a ex_pu4a ex_pu5a sa_pu1 sa_pu2 sa_pu3 sa_pu4 sa_pu5 ;*/
run;
proc sort data=dm14a out=dm14a1;by usubjid;run;
data dm14a;
set dm14a1;
by usubjid;
if last.usubjid;
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_pucatl(keep=usubjid exdose);
set ex1ba;

if exdose=-9 then
  exdose=0;
else if exdose eq . then
  delete;

/*else if exdose=-1 then exdose=.;*/
stdy=svendy_190-6+1;

if exdose>2 then
  output ex_pucatl;
else output ex_p1;
run;

proc sort data=ex_pucatl 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_pucatl ,stdy,(((calculated count)*100/stdy)as per
  from ex_p1 where usubjid not in(select distinct usubjid from ex_pucatl/*ex1b1 where exdose>2*/) group by usubjid,stdy; /*avg
  _pucatl is used for deriving the pucatl*/
quit;

proc sort data=lb out=lb1a;
  by usubjid;
  where lbtestcd="C0" /*and lbstresn>10*/;
run;

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```

data lb_p2a;
merge lb1a(in=a) sv130 sv160 sv190;
by usubjid;

if a;

if svendy_130 eq . then
svendy_130=31;

if svendy_160 eq . then
svendy_160=61;

if svendy_190 eq . then
svendy_190=91;
run;

proc sort data=lb_p2a out=lb_1a(keep=usubjid)nodupkey;
by usubjid;
where lbtestcd="C0" and (6<lbdy<=svendy_190) and lbstresn<=10;
run;

proc sort data=lb_p2a out=lb_1b(keep=usubjid)nodupkey;
by usubjid;
where lbtestcd="C0" and (6<lbdy<=svendy_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;
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 su
_n1(in=i);
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/*,su_pu1*/) ne 0 then do;
ex_pu1a=(dx_pu1/(exdose_sum+dx_pu1/*+su_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 if b and pucat1 eq " " then pucat1="Abstinent";
else if base_dose>0 then pucat1='Primarily CC' ;
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 if b and gpucat1 eq " " then gpucat1="Abstinent";
else if base_dose>0 then gpucat1='CC' ;
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 /*c and*/ .<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 pucat1 eq " "*/ and su_pu1 <= 0 and ex_pu1<=0 then pucat1="Abstinent";

```

```

        if pucat1 eq " " then do;
            if (not b and h and a and 0<=avg_pucat<=0.5) or not(a and i) then do;
                pucat1="Predominantly Abstinent";
                gpucat1="Predominantly Abstinent";*/
            end;
        end;
    end;
end;

```

```

        if pucat1 eq " " then pucat1="Not Abstinent";
/*      if gpucat1 eq " " then gpucat1="Not Abstinent"; */

```

```

if gpucat1 eq " " then do;
if b /*and gpucat1 eq " "*/and su_pu1 <= 0 and ex_pu1<=0 then gpucat1="Abstinent";

```

```

if gpucat1 eq " " then do;
    if (not b and h and a and .<avg_pucat<=0.5) or not (a and i) then do;
        gpucat1="Predominantly Abstinent";
    end;
end;
end;

```

```

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

```

```

end;
if b and pucat1 eq " " then pucat1="Abstinent";
if b and gpucat1 eq " " then gpucat1="Abstinent";

```

```

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=" " then do;
    pucat1="Not Abstinent";
    gpucat1="Not Abstinent";
    *pucat1=13;
end;

```

```

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

```

```

if gpucat1 ne " " then
    gpucat1n=input(put(gpucat1,$ccgpucat.),best.);
/* if armcd not in("SMABST") and pucat1n=10 then pucat1n=13; */
/* if armcd not in("SMABST") and gpucat1n=4 then gpucat1n=7; */

```

```

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=,per=);

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 m
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";
/* &gpucat.="Predominantly Abstinent"; */

end;
end;

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

if &gpucat. = " " then do;
if base_dose>0 then &gpucat.="CC";
end;
/*if &ex_pu. eq . then do;
&pucat.="Predominantly Abstinent";
&gpucat.="Predominantly Abstinent";
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 &pucat. eq " "*/ and not (ex or dx or nrt) then do;
&pucat.="Abstinent";
&gpucat.="Abstinent";
end;

```

```

if &pucat. eq " " then do;
if c and perd /*and .<avg_<=0.5*/ and /*not (nrt)*/MAX_NONRT<=2 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;

if &pucat. ne " " then
    &pucatn.=input(put(&pucat.,$mccpucatn.),best.);
/* if armcd not in("SMABST") and &pucatn.=10 then &pucatn.=13;*/

if &gpucat. ne " " then
    &gpucatn.=input(put(&gpucat.,$ccgpucatn.),best.);
/* if armcd not in("SMABST") and &gpucatn.=4 then &gpucatn.=7;*/
keep usubjid &pucat.: &gpucat.: &pucatex.;
run;

%mend;

proc sort data=lb_p2a out=lb_3a(keep=usubjid) nodupkey;
    by usubjid;
    where lbtestcd="C0" and (svendy_130<lbdy<=svendy_160) and lbstresn>10;
run;
proc sort data=lb_p2a out=lb_3b(keep=usubjid) nodupkey;
    by usubjid;
    where lbtestcd="C0" and (svendy_130<lbdy<=svendy_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="C0" and (6<lbdy<=svendy_130/*31*/) and lbstresn>10;
run;
proc sort data=lb_p2a out=lb_2b(keep=usubjid) nodupkey;
    by usubjid;
    where lbtestcd="C0" and (6<lbdy<=svendy_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="C0" 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="C0" 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="C0" 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="C0" and (6<lbdy<=svendy_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<=svendy_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<=svendy_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=pucat
2ex,in_su=su_pu2, in_expu=ex_pucat2 ,in_expuavg=expucat2_avg, pucat=pucat2 ,pucatn=pucat2n,gpucat=gpucat2,gpucatn=gpucat2n,d
%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,gpu
%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,gpu
%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

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 /*RFSTDTC*/ 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=propcase(lvisit);
run;

data vd;
set crf.vd_disch;
length usubjid $24.;
usubjid=strip(project)||"-"||strip(sitenumber)||"-"||strip(subject);
keep usubjid visdat distim;
run;

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

data vd_en(drop=visdat distim);
set vd;
by usubjid visdat distim;
if last.usubjid;

```

```

if distim ne " " then vsdat=dhms(datepart(visdat),input(scan(distim,1,":"),best.),input(scan(distim,2,":"),best.),0);
else vsdat=dhms(datepart(visdat),0,0,0);
format vsdat datetime13.;
run;
/*as per pmi comment if SA arm subject is discontinued on DAY 1 then set TRTSDTM to the max(10:00,study discharge time)*/
data vd_st(drop=visdat);
set vd;
by usubjid visdat distim;
if first.usubjid;
if distim ne " " and visdat ne . then vsdat_st=dhms(datepart(visdat),input(scan(distim,1,":"),best.),input(scan(distim,2,":"),best.),0);
else if distim eq " " and visdat ne . then vsdat_st=dhms(datepart(visdat),10,0,0);

format vsdat_st datetime13.;
run;
data dm16b;
merge dm16a(in=a) vd_en(in=b) vd_st(in=c);
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 TRT
EDTM we should assign the min time from VISit of Discharge folder */
if DISCCAT not in (" ","Completed") and trt01a="SA" and distim ne " " then do;
trtedtm=max(datepart(trtedtm),vsdat);
trtetmf=" ";
trtedt=datepart(trtedtm);
trteday=trtedt-input(rfstdt,yyymmdd10.)+1;
end;
if TRT01A="SA" then do;
if disccat="Discontinued Period 1 with randomized product use" then trtsdtm=min(trtsdtm,vsdat_st);
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;
if pucat1ex ne " " then pucat1ex="";
if pucat2ex ne " " then pucat2ex="";
if pucat3ex ne " " then pucat3ex="";
if pucat4ex ne " " then pucat4ex="";
if pucat5ex ne " " then pucat5ex=" ";

end;

if disccat eq ("Discontinued Period 2") then do;
pucat3="Missing";pucat4="Missing";pucat3n=99;pucat4n=99;gpucat3="Missing";gpucat4="Missing";gpucat3n=99;gpucat4n=99;
pucat5="Missing";pucat5n=99;
gpucat5="Missing";gpucat5n=99;
pucat3ex=" "; pucat4ex=" "; pucat5ex=" ";

end;

if disccat eq ("Discontinued Period 3") then do;
pucat4="Missing";pucat4n=99;gpucat4="Missing";gpucat4n=99;
pucat5="Missing";pucat5n=99;
gpucat5="Missing";gpucat5n=99;
pucat4ex=" "; pucat5ex=" ";
end;
run;
data adsl;
set dm16c;
format bmi exfl exnotrfl dsreasp ;
length QUITSMOK $2.QTSMKDY 8.;
QUITSMOK=" ";
QTSMKDY=.;

```

```

run;

%m_attrib_adam(dset=ADSL);

data adsl;
set adsl;
label pucat1 ="Product Use Cat.1-Ambulatory,Safety";
label pucat1n= "Product Use Cat.1-Ambulatory,Safety(N)";
run;

/* QUITSMOK QTSMKDY added on 29July2015*/

data dx_q;
set sdtm.dx;
if dxдостxt ne " " then dxdose_=input(dxдостxt,best.);
else dxdose_=dxdose;
keep usubjid dxdose dxдостxt dxdose_ dxstdy;
run;

proc sort data=dx_q; by usubjid ; where dxdose_ > 0; run;

data dx_q1;
set dx_q;
by usubjid;
if last.usubjid;
keep usubjid dxdose_ dxstdy;
run;

data ex_q;
set sdtm.ex;
if exдостxt ne " " then exdose_=input(exдостxt,best.);
else exdose_=exdose;
keep usubjid exdose exдостxt exdose_ exstdy;
run;
proc sort data=ex_q; by usubjid ; where exdose_>0; run;

data ex_q1;
set ex_q;
by usubjid;
if last.usubjid;
keep usubjid exdose_ exstdy;
run;
Proc sort data=adsl out=adsl1; by usubjid; run;

proc sort data=sdtm.sv out=sv_(keep=usubjid svendy visitnum visit );by usubjid visitnum;
where index(visit,"UNSCHEDULED" )=0;
run;

data sv_1;
set sv_;
by usubjid visitnum;
if last.usubjid;
run;

data adsl2(drop=exdose_ exstdy dxdose_ dxstdy svendy visit visitnum);
merge adsl1(in=a drop=QUITSMOK QTSMKDY) dx_q1 ex_q1 sv_1;
by usubjid;
length QUITSMOK $2.QTSMKDY 8.;
if a;

if TRT01A eq "THSm2.2" then do;
    if svendy > max(dxstdy,exstdy)+1 then quitsmok="Y" ;
    else quitsmok="N";
    if quitsmok="Y" then qtsmkdy=max(dxstdy,exstdy)+1;
end;
if trt01a eq "mCC" then do ;
    if svendy > exstdy+1 then quitsmok="Y" ;
    else quitsmok="N";
    if quitsmok="Y" then qtsmkdy=exstdy+1;

end;

label QUITSMOK="Quit Smoking THS and mCC";
label QTSMKDY="Day Quit Smoking THS and mCC";

```

```
run;

data adam.adsl(label="Subject Level Analysis Dataset");
set adsl2;
run;
proc compare base=adam.adsl compare=qadam.qadsl outbase outcomp outdiff outnoequal out=compare;
run;

%m_logchk;
```