

```

options notes nosource;
proc datasets lib=work nolist memtype=data kill; quit;
* macro to save output and log to appropriate areas ;
%_mprintto;
%put NOTE:
=====;
%put NOTE: Covance Study Number : 000000106326;
%put NOTE: Client Protocol ID   : ZRHM-PK-05-JP;
%put NOTE: Program Name        : d_1ADSL.sas;
%put NOTE: Purpose              : create ADSL dataset;
%put NOTE: ;
%put NOTE: Input Data           : STDLIB.ADSL SDTM.DM SDTM.SUPPDM SDTM.VS
SDTM.FA SDTM.CM;
%put NOTE:
      SDTM.EX SDTM.DX SDTM.DS SDTM.SV SDTM.IE SDTM.LB SDTM.SUPPDS;
%put NOTE: Output               : ADAM.ADSL;
%put NOTE: Macros Called        : _MPRINTTO _SCRAMBLE;
%put NOTE: ;
%put NOTE: Programmed by        : cvn_jriley;
%put NOTE: Creation Date        : 2014-01-03;
%put NOTE: SAS Version          : 9.3;
%put NOTE: ;
%put NOTE: == Latest Run
=====;
%put NOTE: Run by               : &sysuserid;
%put NOTE: Date/Time            :
%sysfunc(putn(%sysfunc(date()),e8601da.))T%sysfunc(putn(%sysfunc(time()),
e86011z.));
%put NOTE: ;
%put NOTE: == Modification History
=====;
%put NOTE: Date      Initials   No. Reason;
%put NOTE: 09Jan2014   JMH       1) Added and corrected wa-rnings to
pick up problems;
%put NOTE: 09Jan2014   JMH       2) Amended code for RACEN as it will
be blank in this study;
%put NOTE: 09Jan2014   JMH       3) Amended mapping of ARMCDN and
TRXXPN;
%put NOTE: 09Jan2014   JMH       4) Amended NICOGR1;
%put NOTE: 09Jan2014   JMH       5) Amended TRxxSDT/TRxxEDT when no
time is in SDTM;
%put NOTE: 09Jan2014   JMH       6) Amended safety flag in line with
SAP;
%put NOTE: 09Jan2014   JMH       7) Amended EXFL in line with shell;
%put NOTE: 10Jan2014   JMH       8) Amended TRxxPN;
%put NOTE: 10Jan2014   JMH       9) Added wa-rnings to pick up
problems;
%put NOTE: 10Jan2014   JMH       10) Amended assignment of trtseqa for
when trt02a is missing;
%put NOTE: 10Jan2014   JMH       11) Amended inclusion/exclusion data
for protocol dev flag;
%put NOTE: 10Jan2014   JMH       12) Dropped FATESTCD and EPOCH as
they are not in the spec;
%put NOTE: 10Jan2014   JMH       13) Amended EXFL in line with shell;

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%put NOTE: 10Jan2014	JMH	14) Amended TRxxPN;
%put NOTE: 10Jan2014	JMH	15) Amended SAFFL;
%put NOTE: 10Jan2014	JMH	16) Amended TRxxP to be consistent
with TRxxA ;		
%put NOTE: 10Jan2014	JMH	17) Amended TRxxSDT/TRxxEDT when no
time is in SDTM;		
%put NOTE: 10Jan2014	JMH	18) Brought in FA dataset to see if
subjects had product test;		
%put NOTE: 12Jan2014	KB	19) Amended TR01SDT to be TR02SDT;
%put NOTE: 12Jan2014	KB	20) Amended derivation of product
test;		
%put NOTE: 13Jan2014	JMH	21) Amended Scramble macro;
%put NOTE: 13Jan2014	JMH	22) Kept in subjects who were unable
to do tests, kept dates;		
%put NOTE: 13Jan2014	JMH	23) Amended treatment labels;
%put NOTE: 14Jan2014	JMH	24) Amended safreas;
%put NOTE: 14Jan2014	JMH	25) Amended code for ENRLFL;
%put NOTE: 14Jan2014	KB	26) Amended length of SAFREAS;
%put NOTE: 14Jan2014	KB	27) Amended merge;
%put NOTE: 15Jan2014	KB	28) Amended compliance flags for if
there are missing LB results;		
%put NOTE: 15Jan2014	KB	29) Added in temporary fix for
subjects on NRT gum, set PPROFL and PPREAS to blank;		
%put NOTE: 15Jan2014	JMH	30) Dropped WILLABL;
%put NOTE: 12Apr2014	KB	31) Added randomisation number;
%put NOTE: 12Apr2014	KB	32) Amended RACE;
%put NOTE: 12Apr2014	KB	33) Amended baseline weight;
%put NOTE: 12Apr2014	KB	34) Added time imputation flags;
%put NOTE: 12Apr2014	KB	35) Amended format of TRTSDTM;
%put NOTE: 12Apr2014	KB	36) Added PPREAS for non-randomized
subjects;		
%put NOTE: 12Apr2014	KB	37) Amended TRTSEQA for if the subject
withdraws;		
%put NOTE: 12Apr2014	KB	38) Amended UCPDGR1;
%put NOTE: 12Apr2014	KB	39) Amended DISCDT;
%put NOTE: 12Apr2014	KB	40) Amended device and gum tests;
%put NOTE: 12Apr2014	KB	41) Included performed test data to
EXFL;		
%put NOTE: 12Apr2014	KB	42) Removed DS from merge;
%put NOTE: 12Apr2014	KB	43) Amended NICOGR1;
%put NOTE: 12Apr2014	KB	44) Amended COMPL0FL and COMPL2FL;
%put NOTE: 12Apr2014	KB	45) Amended nicotine replacement gum to
nicotine replacement therapy;		
%put NOTE: 12Apr2014	KB	46) Amended NRTFAIL variable;
%put NOTE: 12Apr2014	KB	47) Added variables to scramble macro;
%put NOTE: 12Apr2014	KB	48) Added variables to drop;
%put NOTE: 12Apr2014	KB	49) Amended capital G in gum;
%put NOTE: 12Apr2014	KB	50) Amended ARM to ARMCD;
%put NOTE: 12Apr2014	KB	51) Amended TRTSEQP and TRTSEQA;
%put NOTE: 12Apr2014	KB	52) Amended problems in log with merge;
%put NOTE: 12Apr2014	KB	53) Amended capitalisations in SAFREAS;
%put NOTE: 15Apr2014	KB	54) Amended formats for variables;
%put NOTE: 22Apr2014	KB	55) Given formats to HEIGHT WEIGHTBL
and compliance flags;		

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%put NOTE: 22Apr2014    KB          56) Amended COMPL1FL and COMPL3FL;
%put NOTE: 04Jun2014    SM          57) Add in specific code for change to
PPROTFL and PPREAS;
%put NOTE: 04Aug2014    KB          58) Used FLOOR on TARBL for TARGR1;
%put NOTE: 04Aug2014    KB          59) Amended ENRLFL derivation;
%put NOTE: 04Aug2014    KB          60) Added EXNOTRFL;
%put NOTE: 04Aug2014    KB          61) Added NICOGR2;
%put NOTE: 04Aug2014    KB          62) Amended IE criteria for PPROTFL to
match 02 & commented out an old section;
%put NOTE: 04Aug2014    KB          63) Amended COMPLxFL;
%put NOTE: 04Aug2014    KB          64) Commented out old TRTSEQ code;
%put NOTE: 04Aug2014    KB          65) Amended FUPFL;
%put NOTE: 04Aug2014    KB          66) Amended datetimes due to old format
not working;
%put NOTE: 04Aug2014    KB          67) Dropped variables not required;
%put NOTE: 04Aug2014    KB          68) Removed format from DMRANDNO;
%put NOTE: 04Aug2014    KB          69) Amended length warnings in log;
%put NOTE: 06Aug2014    KB          70) Amended NICOGR1;
%put NOTE: 06Aug2014    KB          71) Amended PPREAS by adding else to if
chain;
%put NOTE: 06Aug2014    KB          72) Added ARMCDN for NOTASSGN;
%put NOTE: 06Aug2014    KB          73) Amended LVISDT to use SVENDTC;
%put NOTE: 06Aug2014    KB          74) Amended COMPL0FL;
%put NOTE: 07Aug2014    KB          75) Amended update 70;
%put NOTE: 07Aug2014    KB          76) Added to update 74;
%put NOTE: 08Aug2014    KB          77) Amended formats of DTESTTM &
PTESTTM;
%put NOTE: 21Sep2014    KB          78) Amended derivation of DTESTDTM &
PTESTDTM as SDTM data is to seconds;
%put NOTE: 21Sep2014    KB          79) Amended issue with lowercase t in
scan;
%put NOTE: 21Sep2014    KB          80) Added a warning to log if TRTSEQA
ne TRTSEQP;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

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

*****
*****;
* pick up demography data ;
* create numeric variables and code according to value level metadata in
ADaM specs ;
*****
*****;
data dm;
    set sdtm.dm;
    format subjidn sexn racen armcdn ethnictn 8. brthdt date9. sexc $20.

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        rfstdt date9.;
subjdn = input(subjid,best.);
brthdt = input(brthdtc,ymmdd10.);
if sex = 'M' then do;
    sexc = 'Male';
    sexn = 1;
end;
else if sex = 'F' then do;
    sexc = 'Female';
    sexn = 2;
end;
ELSE PUT "WA" "RNING: Unexpected value " SUBJIDN= SEX= ; /*1) JMH
09Jan2014*/

/*RACE=''; */ /*STUDY SPECIFIC. PK-05*/ /*2) JMH 09Jan2014*/ /* 32)
KB 12Apr2014 */
/* RACEN=''; */ /*STUDY SPECIFIC. PK-05*/ /*2) JMH 09Jan2014*/ /* 32)
KB 12Apr2014 */

/* 32) START KB 12Apr2014 */
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;
ELSE PUT "Check demography for races";
/* 32) END KB 12Apr2014 */

if ethnic='CAUCASIAN' then ethnkn=1;
else if ethnic='NOT CAUCASIAN' then ethnkn=2;
else if ethnic = 'JAPANESE' then ethnkn = 3;
else if ethnic = 'NOT JAPANESE' then ethnkn = 4;
else if ethnic = 'HISPANIC' then ethnkn=5;
else if ethnic = 'NOT HISPANIC' then ethnkn=6;
else if (missing(ethnic) and armcd ne 'SCRNFAIL') or not
missing(ethnic) then put 'USER WA' 'RNING: Check Ethnicity for controlled
terms: ' usubjid = ethnic = ;

*study reference dates ;
/* if not missing(rfstdtc) and length(rfstdtc) gt 10 then rfstdt =
datepart(input(rfstdtc,is8601dt.)); */
IF NOT MISSING(RFSTDTC) AND LENGTH(RFSTDTC) GT 10 THEN RFSTDTC =
DATEPART(DHMS(INPUT(SCAN(RFSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(RFSTDTC,2,'T'),TIME5.)),MINUTE(INPUT(SCAN(RFSTDTC,2,'T'),TIME5.)),0)) ; /* 66)
KB 04Aug2014 */
else if not missing(rfstdtc) and length(rfstdtc) = 10 then rfstdt =
input(rfstdtc,ymmdd10.);

* numeric arm coding variables
* study specific;
if armcd = 'THS 2.2M - MCC' then armcdn = 14;
else if armcd = 'MCC - THS 2.2M' then armcdn = 15;

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        else if armcd = 'THS 2.2M - NRT GUM' then armcdn = 16/*18*/; /*3)
JMH 09Jan2014*/
        else if armcd = 'NRT GUM - THS 2.2M' then armcdn = 17/*19*/; /*3)
JMH 09Jan2014*/
        else if armcd = 'SCRNFAIL' then armcdn = 4;
        ELSE IF ARMCD = "NOTASSGN" THEN ARMCDN = 20; /* 72) KB 06Aug2014 */
        else if missing(armcd) then put /*'WA' 'RNNING:*/ 'WA' 'RNING:
Check DM, missing armcds';/*1) JMH 09Jan2014*/

        keep studyid usubjid subjid subjidn siteid age ageu brthdtc brthdt
sex sexc sexn race racen ethnic: country arm
        armcd armcdn rfstdt dthfl;
run;
/* 31) START KB 12Apr2014 */
DATA RANDNO;
    SET SDTM.SUPPDM(WHERE=(QNAM='DMRANDNO'));
/*    FORMAT DMRANDNO $10.;*/ /* 68) KB 04Aug2014 */

    IF QNAM='DMRANDNO' THEN DMRANDNO=COMPRESS(QVAL);

    KEEP USUBJID DMRANDNO;
RUN;

DATA DMA;
    MERGE DM(IN=A) RANDNO;
    BY USUBJID;
    IF A;
RUN;
/* 31) END KB 12Apr2014 */
*****;
* pick up if race=other for specify details ; /*This code will be used
if SUPPDM is available*/
* macro to check if SUPPDM dataset exists ; /*It is being
left in the code to carry through to all studies*/
*****; /*If SDTM.SUPPDM
exists then comment out this code. Otherwise, leave commented*/
/*%macro _mcheckdata(dset1=, dset2=);*/

/*%let no = 0; /* does suppdm exist ;
/*%let racecheck = 0; /* does race=OTHER exist ;
/**/
/*data _null_*/
/*    set dm;*/
/*    if race = 'OTHER' then call symput('racecheck','1');*/
/*run;*/

/*%if &racecheck. = 1 %then %do; /* race=OTHER exists ;

/*data _null_*/
/*    if (exist("&dset1..", "SDTM")) then do;*/
/*    put "USER NO" "TE &dset1 does exist.";*/
/*    dsid = open("&dset1.", 'I'); /*remove condition if not
searching for any records;
/*    rc = fetch(dsid);*/

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/*      if rc = -1 then do;*/
/*      put "USER WARN" "ING &dset1. has no data.";*/
/*      call symput('no',0);*/
/*      end;*/
/*      else do;*/
/*      call symput('no',1);*/
/*      end;*/
/*      rc = close(dsid);*/
/*      return;*/
/*      end;*/
/*      else do;*/
/*      put "USER WARN" "ING &dset1. does not exist.";*/
/*      call symput('no',0);*/
/*      stop;*/
/*      end;*/
/* run;*/

```

\* if data has indicated OTHER is present in race then check to make sure SUPPDM exists;

\* write a note to the log if not ;

```

/*%if &racecheck. = 1 and &no. ne 1 %then %put "USER WARN" "ING: Data
indicates OTHER race present but &dset1. does not exist";*/

```

\* if SUPP file does exist ;

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/*%if &no. = 1 %then %do;*/
/*      proc transpose data = sdtm.&dset1. out = &dset1.a;*/
/*      by usubjid idvarval;*/
/*      id qnam;*/
/*      var qval;*/
/*      run;*/
/**/
/*      proc sort data = &dset1.a;*/
/*      by usubjid;*/
/*      run;*/
/**/
/**/
/*      data &dset2.a;*/
/*      merge &dset2. &dset1.a;          */
/*      by usubjid;*/
/*      if index(race,'OTHER') and missing(raceoth) then put 'USER
WARN' 'ING: Other information missing - query with DM: ' usubjid; */
/*      run;*/
/*%end;*/
/*%end;*/
* if SUPP file does not exist;
/*%if &no. = 0 %then %do;*/
/**/
/*%if &racecheck. = 0 %then %put 'USER NOTE: race = OTHER does not
exist';*/

```

```

/**/
/*    data &dset2.a;*/
/*        set &dset2.;*/
/*    run;*/
/*%end;*/
/**/
/*%mend _mcheckdata;*/
/*%_mcheckdata(dset1=suppdm, dset2=dm);*/

*****
*****;
* Bring in vital signs data for weight height and BMI ;
* baseline is usually screening - check for study specific requirements ;
*****
*****;
/* 33) START KB 12Apr2014 */
DATA WEIGHT;
    SET SDTM.VS(WHERE=(VSTESTCD IN ('HEIGHT' 'WEIGHT')));

    IF VSTESTCD='WEIGHT' AND VISIT NE 'DAY -1' THEN DELETE;
RUN;
/* 33) END KB 12Apr2014 */

proc transpose data = /*sdtm.vs*/WEIGHT/*(where=(vsblfl='Y' and vstestcd
in ('WEIGHT' 'HEIGHT' 'BMI')))*/* out = tvs (drop=_: rename = (weight =
weightbl)); /* 33) KB 12Apr2014 */
    var vsstresn;
    by usubjid;
    id vstestcd;
run;

*****;
* produce derived classification parameters for BMI ;
*****;
data vs2;
    set tvs;
    format bmigrl $40. bmigrln 8. BMI 8.1 HEIGHT WEIGHTBL BEST.; /* 33)
KB 12Apr2014 */ /* 55) KB 22Apr2014 */

    BMI=WEIGHTBL/((HEIGHT/100)**2); /* 33) KB 12Apr2014 */

    if 0 < bmi < 18.5 then do;
        bmigrl = 'Underweight';
        bmigrln = 1;
    end;
    else if 18.5 <= bmi < 25 then do;
        bmigrl = 'Normal weight';
        bmigrln = 2;
    end;
    else if 25 <= bmi < 30 then do;
        bmigrl = 'Overweight';
        bmigrln = 3;
    end;
    else if bmi >= 30 then do;

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        bmigr1 = 'Obese';
        bmigrln = 4;
    end;
    else if not missing(bmi) then put 'USER WARN' 'ING BMI
unclassified: ' usubjid= bmi=;
run;

*****;
* add to DM ;
*****;

data dm2;
    merge /*dm*/DMA(in = a) vs2(in = b); /* 31) KB 12Apr2014 */
    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 ;
*****
*****;

data fa(keep = usubjid ucpdgr:);
    set sdtm.fa(where=(faobj = 'SMOKING HISTORY' and fatestd =
'SMOKHIST' and epoch='ADMI'));
    format ucpdgr1 $40. ucpdgrln 8.;
    if index(/*fastresc*/FAORRES,'<10') then do; /* 38) KB 12Apr2014 */
        ucpdgrln = 1;
        ucpdgr1 = '<10 cig/day';
    end;
    else if /*fastresc*/FAORRES = '10 to 19' then do; /* 38) KB
12Apr2014 */
        ucpdgrln = 2;
        ucpdgr1 = '10-19 cig/day';
    end;
    else if index(/*fastresc*/FAORRES,'>19') then do; /* 38) KB
12Apr2014 */
        ucpdgrln = 3;
        ucpdgr1 = '>19 cig/day';
    end;
    else put 'USER WARN' 'ING unable to classify daily cigarette
consumption: ' usubjid= fastresc=;
    output; * only keep usual
daily cig consumption;
run;

*****;

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* add to DM2 ;
*****;

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 fal(keep = usubjid nico: fatestdcd epoch);
    set sdtm.fa(where = (index(fatestcd,'NYIELD'/'YIELD'*/) and epoch
= 'ADMI')); /*4) JMH 09Jan2014*/
    format nicobl best8. nicogrln NICOGR2N 8. nicogr1 NICOGR2 $20.; /*
61) KB 04Aug2014 */
    nicobl = fastresn;
    if not missing(nicobl) and nicobl le 0.6 then do;
/*        nicogr1 = '<= 0.6 mg';*/
        NICOGR1 = /*'<=0.6 mg'/'<= 0.6 mg'; /*4) JMH 09Jan2014*/ /*
43) KB 12Apr2014 */
        nicogrln = 1;
    end;
    else if 0.6 < nicobl <= 1 then do;
/*        nicogr1 = '> 0.6 mg - <= 1.0 mg';*/
        NICOGR1 = /*'>0.6 mg - 1.0 mg'/'> 0.6 mg - <= 1.0
mg'/'> 0.6 - <= 1.0 mg'/'> 0.6 - 1.0 mg'; /*4) JMH 09Jan2014*/ /* 43)
KB 12Apr2014 */ /* 70) KB 06Aug2014 */ /* 75) KB 07Aug2014 */
        nicogrln = 2;
    end;
    else if nicobl > 1 then do;
/*        nicogr1 = '> 1.0 mg';*/
        nicogr1 = /*'>1.0 mg'/'> 1.0 mg'; /*4) JMH 09Jan2014*/ /*
43) KB 12Apr2014 */
        nicogrln = 3;
    end;

/* 61) START KB 04Aug2014 */
    IF NOT MISSING(NICOBL) AND NICOBL LE 1.0 THEN DO;
        NICOGR2 = '<= 1.0 mg';
        NICOGR2N = 1;
    END;
    ELSE IF NICOBL > 1.0 THEN DO;
        NICOGR2 = '> 1.0 mg';
        NICOGR2N = 2;
    END;
/* 61) END KB 04Aug2014 */

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        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 = (fatestcd = 'TYIELD' and epoch = 'ADMI'));
    format tarbl targrln 8. targr1 $20.;
    tarbl = fastresn;
    if 1 le FLOOR(tarbl) le 5 then do; /* 58) KB 04Aug2014 */
        targr1 = '1-5 mg';
        targrln = 1;
    end;
    else if 6 le FLOOR(tarbl) le 8 then do; /* 58) KB 04Aug2014 */
        targr1 = '6-8 mg';
        targrln = 2;
    end;
    else if 9 le FLOOR(tarbl) le 10 then do; /* 58) KB 04Aug2014
*/
        targr1 = '9-10 mg';
        targrln = 3;
    end;
    else if FLOOR(tarbl) gt 10 then do; /* 58) KB 04Aug2014 */
        targr1 = '>10 mg';
        targrln = 4;
    end;
    else put 'USER WARN' 'ING unable to classify tar yield at baseline:
' usubjid= tarbl=;
    output;                                * only keep tar yield
information;
run;

*****;
* add to DM3 ;
*****;

data dm4;
    merge dm3(in = a) fa1(in = b) fa2(in = c);
    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=;

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        end;
run;

*****;
* bring in exposure data ;
*****;
* device admin data;
data dx;
    set sdtm.dx(where = (not missing(dxstdtc) and dxstdy ge 1));    *
don't include device test data ;
    LENGTH EXCAT $31 EXENDTC $19; /* 69) KB 04Aug2014 */
    EXCAT=DXTRT; /* 69) KB 04Aug2014 */
    EXENDTC=DXENDTC; /* 69) KB 04Aug2014 */
run;

proc sort data = dx;
    by usubjid;
run;

* mcc admin data ;
data mex;
    set sdtm.ex(where=(exstdy ge 1 and not missing(exstdtc) and excat
eq 'MENTHOL CONVENTIONAL CIGARETTES'));* don't include admission data for
mcc data ;
run;

proc sort data = mex;
    by usubjid;
run;

* nicotine gum data ;
data nrt;
    set sdtm.ex(where=(exstdy ge 1 and not missing(exstdtc) and excat
eq 'NICOTINE REPLACEMENT THERAPY'));* don't include admission data for
gum data ;
run;

proc sort data = nrt;
    by usubjid;
run;

* combine for full product admin set ;
data exp;
    set dx(rename = (dxstdtc = exstdtc /*dxendtc = exendtc*/
dxstdy=exstdy /*dxtrt=excat*/)) mex nrt; /* 69) KB 04Aug2014 */
    by usubjid;
    keep usubjid exstdtc exendtc exstdy excat;
run;

* sort in date order ;
proc sort data = exp;
    by usubjid exstdy exstdtc exendtc;
run;

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proc transpose data=exp out=texp_1 prefix=t;
    var excat;
    by usubjid;
    id exstdy;
run;

proc transpose data=exp out=texp_2 prefix=s;
    var exstdtc;
    by usubjid;
    id exstdy;
run;

proc transpose data=exp out=texp_3 prefix=e;
    var exendtc;
    by usubjid;
    id exstdy;
run;

data texp2;
    merge texp_1 texp_2 texp_3;
    by usubjid;
    drop _name_ _label_;
run;

data trtd;
    set sdtm.dm;

    format /*trtsdtm*/ trtedtm datetime13. TRTSDTM DATETIME16. trtsdt
trtedt date9. trtsday trteday 8. TRTSTMF $1.; /* 34) KB 12Apr2014 */ /*
35) KB 12Apr2014 */

    /* 34) START KB 12Apr2014 */
    IF NOT MISSING(RFSTDTC) THEN DO;
        TRTS1=SCAN(RFSTDTC,2,'T');
    /*
        IF LENGTH(TRTS1)=8 THEN TRTSDTM=INPUT(RFSTDTC,IS8601DT.);*/
        IF LENGTH(TRTS1)=8 THEN
TRTSDTM=DHMS(INPUT(SCAN(RFSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(RFSTDTC
,2,'T'),TIME5.)),MINUTE(INPUT(SCAN(RFSTDTC,2,'T'),TIME5.)),0); /* 66) KB
04Aug2014 */
        ELSE IF LENGTH(TRTS1)<8 THEN DO;
            TRTS1=CATS(RFSTDTC,':30');
    /*
            TRTSDTM=INPUT(TRTS1,IS8601DT.);*/

TRTSDTM=DHMS(INPUT(SCAN(RFSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(RFSTDTC
,2,'T'),TIME5.)),MINUTE(INPUT(SCAN(RFSTDTC,2,'T'),TIME5.)),0); /* 66) KB
04Aug2014 */
            TRTSTMF='S';
        END;
    END;
END;
/*
    if not missing(rfstdtc) then do;*/
/*
        trtsdtm=input(rfstdtc,is8601dt.);*/
/*
    end;*/
/* 34) END KB 12Apr2014 */
    trtsdt=datepart(trtsdtm);

```

```

        if not missing(rfendtc) then do;
/*          trtedtm=input(rfendtc,is8601dt.);*/

        TRTEDTM=DHMS (INPUT (SCAN (RFENDTC,1,'T'),YYMMDD10.),HOUR (INPUT (SCAN (R
FENDTC,2,'T'),TIME5.)),MINUTE (INPUT (SCAN (RFENDTC,2,'T'),TIME5.)),0); /*
66) KB 04Aug2014 */
        end;
        trtedt=datepart(trtedtm);

        if not missing(rfstddtc) then do;
/*          trtsday=trtsdt - datepart(input(rfstddtc,is8601dt.))+1;*/
/*          trteday=trtedt - datepart(input(rfstddtc,is8601dt.))+1; */
        TRTSDAY=TRTSDT -
DATEPART (DHMS (INPUT (SCAN (RFSTDTC,1,'T'),YYMMDD10.),HOUR (INPUT (SCAN (RFSTDTC,2,'T'),TIME5.)),MINUTE (INPUT (SCAN (RFSTDTC,2,'T'),TIME5.)),0))+1; /* 66)
KB 04Aug2014 */
        TRTEDAY=TRTEDT -
DATEPART (DHMS (INPUT (SCAN (RFSTDTC,1,'T'),YYMMDD10.),HOUR (INPUT (SCAN (RFSTDTC,2,'T'),TIME5.)),MINUTE (INPUT (SCAN (RFSTDTC,2,'T'),TIME5.)),0))+1; /*
66) KB 04Aug2014 */
        end;

        keep usubjid trtsdtm trtsdt trtedtm trtedt trtsday trteday TRTSTMF;
/* 34) KB 12Apr2014 */
run;

data trtd2;
    merge texp2 trtd;
    by usubjid;
run;

data ex2s(keep = usubjid trts: tr01s: tr02s:) ex2e(keep = usubjid trte:
tr01e: tr02e:);
    set trtd2;
    by usubjid;
    format /*tr01sdtm*/ tr01edtm /*tr02sdtm*/ tr02edtm datetime13.
TR01SDTM TR02SDTM DATETIME16. tr01sdt tr01edt tr02sdt tr02edt date9. /*
35) KB 12Apr2014 */
    /*tr01stm*/ tr01etm /*tr02stm*/ tr02etm time5. TR01STM TR02STM
TIME8. TR01STMF TR02STMF $1.; /* 35) KB 12Apr2014 */ /* 34) KB 12Apr2014
*/

        if not missing(s1) /*AND index(s1,'T')*/ then do;
/* 34) START KB 12Apr2014 */
/*          tr01sdtm = input(s1,is8601dt.);*/
        TRTS1=SCAN(S1,2,'T');
/*          IF LENGTH(TRTS1)=8 THEN TR01SDTM=INPUT(S1,IS8601DT.);*/
        IF LENGTH(TRTS1)=8 THEN
TR01SDTM=DHMS (INPUT (SCAN (S1,1,'T'),YYMMDD10.),HOUR (INPUT (SCAN (S1,2,'T'),T
IME5.)),MINUTE (INPUT (SCAN (S1,2,'T'),TIME5.)),0); /* 66) KB 04Aug2014 */
        ELSE IF LENGTH(TRTS1)<8 THEN DO;
            TRTS1=CATS(S1,':30');
/*          TR01SDTM=INPUT (TRTS1,IS8601DT.);*/

```

```

TR01SDTM=DHMS (INPUT (SCAN (TRTS1,1,'T'),YYMMDD10.),HOUR (INPUT (SCAN (TRTS1,2,
'T'),TIME5.)),MINUTE (INPUT (SCAN (TRTS1,2,'T'),TIME5.)),0); /* 66) KB
04Aug2014 */
        TR01STMF='S';
        END;
/* 34) END KB 12Apr2014 */
        tr01sdt = datepart(tr01sdtm);
        tr01stm = timepart(tr01sdtm);
    end;
    /*ELSE IF NOT MISSING(S1) THEN DO;*/ /*5) JMH 09Jan2014*/
    /*      TR01SDT = INPUT (S1,YYMMDD10.)*//*DATEPART (TR01SDTM)*//*;*/
/*17) JMH 10Jan2014*/
/*      END;*/
    if not missing(s3) /*and index(s3,'T')*/ then do;
/* 34) START KB 12Apr2014 */
/*      tr02sdtm = input(s3,is8601dt.);*/
        TRTS2=SCAN(S3,2,'T');
/*      IF LENGTH(TRTS2)=8 THEN TR02SDTM=INPUT (S3,IS8601DT.);*/
        IF LENGTH(TRTS2)=8 THEN
TR02SDTM=DHMS (INPUT (SCAN (S3,1,'T'),YYMMDD10.),HOUR (INPUT (SCAN (S3,2,'T'),T
IME5.)),MINUTE (INPUT (SCAN (S3,2,'T'),TIME5.)),0); /* 66) KB 04Aug2014 */
        ELSE IF LENGTH(TRTS2)<8 THEN DO;
            TRTS2=CATS (S3,':30');
/*      TR02SDTM=INPUT (TRTS2,IS8601DT.);*/

TR02SDTM=DHMS (INPUT (SCAN (TRTS2,1,'T'),YYMMDD10.),HOUR (INPUT (SCAN (TRTS2,2,
'T'),TIME5.)),MINUTE (INPUT (SCAN (TRTS2,2,'T'),TIME5.)),0); /* 66) KB
04Aug2014 */
        TR02STMF='S';
        END;
/* 34) END KB 12Apr2014 */
        tr02sdt = datepart(tr02sdtm);
        tr02stm = timepart(tr02sdtm);
    end;
/*      ELSE IF NOT MISSING(S3) THEN DO;*/ /*5) JMH 09Jan2014*/
        /*TR01SDT*//*TR02SDT =
INPUT (S3,YYMMDD10.)*//*DATEPART (TR02SDTM)*//*;*/ /*17) JMH 10Jan2014*/ /*
19) KB 12Jan2014 */
/*      END;*/
        output ex2s;
        if not missing(e1) /* and index(e1,'T') */ then do;
/*      tr01ledtm = input(e1,is8601dt.);*/
            TR01EDTM =
DHMS (INPUT (SCAN (E1,1,'T'),YYMMDD10.),HOUR (INPUT (SCAN (E1,2,'T'),TIME5.)),M
INUTE (INPUT (SCAN (E1,2,'T'),TIME5.)),0); /* 66) KB 04Aug2014 */
            tr01ledt = datepart(tr01ledtm);
            tr01letm = timepart(tr01ledtm);
        end;
/*      ELSE IF NOT MISSING(E1) THEN DO; *//*5) JMH 09Jan2014*/
        /*      TR01EDT = INPUT (E1,YYMMDD10.)*/
/*DATEPART (TR01EDTM)*//*;*//*17) JMH 10Jan2014*/
/*      END;*/
        if not missing(e3) /* and index(e3,'T')*/ then do;

```

```

/*          tr02edtm = input(e3,is8601dt.);*/
          TR02EDTM =
DHMS(INPUT(SCAN(E3,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(E3,2,'T'),TIME5.)),M
INUTE(INPUT(SCAN(E3,2,'T'),TIME5.)),0); /* 66) KB 04Aug2014 */
          tr02edt = datepart(tr02edtm);
          tr02etm = timepart(tr02edtm);
          end;
/*      ELSE IF NOT MISSING(E3) THEN DO; *//*5) JMH 09Jan2014*/
/*      TR02EDT = INPUT(E3,YYMMDD10.)*/
/*DATEPART(TR02EDTM)*//*;*//*17) JMH 10Jan2014*/
/*      END;*/
          output ex2e;
run;

*****;
* determine actual treatments ;
*****;
*device;
proc sort data = dx;
    by usubjid dxstdy dxstdtc;
run;

data dx2;
    set dx(where = (not missing(dxstdtc)));
    by usubjid dxstdy;
    if first.dxstdy;
run;

proc transpose data = dx2 out = tdx2(drop = _) prefix = d;
    var dxstdtc;
    by usubjid;
    id dxstdy;
run;

*menthol conventional cigarettes;
proc sort data = mex;
    by usubjid exstdy exstdtc;
run;

data ex2;
    set mex(where = (not missing(exstdtc)));
    by usubjid exstdy;
    if first.exstdy;
run;

proc transpose data = ex2 out=tex2(drop = _) prefix=c;
    var exstdtc;
    by usubjid;
    id exstdy;
run;

*nicotine gum data;
proc sort data = nrt;
    by usubjid exstdy exstdtc;

```

```

run;

data nrt2;
    set nrt(where = (not missing(exstdtc)));
    by usubjid exstdy;
    if first.exstdy;
run;

proc transpose data = nrt2 out=tnrt2(drop = _) prefix=n;
    var exstdtc;
    by usubjid;
    id exstdy;
run;

*****;
* add to DM4 ;
*****;

data dm5(drop = rfstdt);
    merge dm4(in = a) ex2s(in = b) ex2e(in = c);
    by usubjid;

    if a and not b then put 'USER WARN' 'ING exposure data not
available: ' usubjid=;
run;

*****;
* introduce DS data for flags and dates for informed consent etc ;
*****;
*all subjects with disposition information;
proc sort data = sdtm.ds out = allds(keep = usubjid) nodupkey;
    by usubjid;
run;

* informed consent;
data infcons;
    merge sdtm.ds(where = (dscat = 'PROTOCOL MILESTONE' and dsdecod =
'INFORMED CONSENT OBTAINED' and dsterm = 'MAIN INFORMED CONSENT') in = a)
        allds;
    by usubjid;
    format icfdtc $20. icfdt date9. icfdtm datetimet13.;
    icfdtc = trim(dsstdtc);
    icfdt = input(dsstdtc, yymmdd10.);
    if length(dsstdtc)>10 then do;
/*          icfdtm = input(dsstdtc,e8601dt.);*/
        ICFDTM =
DHMS(INPUT(SCAN(DSSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(DSSTDTC,2,'T'),
TIME5.)),MINUTE(INPUT(SCAN(DSSTDTC,2,'T'),TIME5.)),0); /* 66) KB
04Aug2014 */
        END;
    else if length(dsstdtc)<10 then do;
        icfdtm = .;
    end;
    keep usubjid icfdtc icfdt icfdtm;

```



```

run;

*****;
* to be enrolled, the subject must comply with all eligibility ;
* criteria (no observations in IE) and have performed a device ;
* test and be willing and able to use the device ;
*****;

* eligibility;
proc sort data = sdtm.ie out = ie(keep = usubjid) nodupkey;
    by usubjid;
run;

* device times;
proc sort data=sdtm.dx(where = (epoch='ADMI'))
out=device/*DEVICE_A*/(keep = usubjid dxstdtc) /*nodupkey*/;/*18) JMH
10Jan2014*/ /* 40) KB 12Apr2014 */
    by usubjid DXSTDTC; /* 40) KB 12Apr2014 */
run;

* nicotine replacement gum times;
proc sort data=sdtm.ex(where = (epoch='ADMI' and excat='NICOTINE
REPLACEMENT THERAPY')) out=gumtest/*GUMTEST_A*/(keep = usubjid exstdtc)
nodupkey; /*18)JMH 10Jan2014*/ /* 40) KB 12Apr2014 */
    by usubjid;
run;

/* 40) START KB 28Mar2014 */
DATA DEVICE1A;
    SET DEVICE;
    BY USUBJID DXSTDTC;

    IF FIRST.DXSTDTC THEN OUTPUT;
RUN;
/* 40) END KB 28Mar2014 */

/*18) START JMH 10Jan2014*/
* device test;
/*PROC SORT DATA=SDTM.FA(WHERE = (EPOCH='ADMI')) OUT=DEVICE_B(KEEP =
USUBJID) NODUPKEY;*/
/*    BY USUBJID;*/
/*RUN;*/
/* 20) START KB 12Jan2014 */
/* 40) START KB 12Apr2014 */
/*PROC SORT DATA=SDTM.FA(WHERE = ((EPOCH='ADMI' AND FATESTCD='PERFORM')
OR (EPOCH='ADMI' AND FATESTCD='WILLABL' AND FACAT='THS 2.2')))*/*
    OUT=DEVICE_B(KEEP = USUBJID FATESTCD FASTRESC FASTAT FADTC);
*//22) JMH 13Jan2014*/
/*    BY USUBJID;*/
/*RUN;*/

/*DATA DEVICE_C;*/
/*    SET DEVICE_B;*/
/*    ATTRIB RESULT FORMAT=$20.;*/

```

```

/**/
/*   IF FASTRESC='' AND FASTAT NE '' THEN RESULT=FASTAT;*/
/*   ELSE IF FASTRESC NE '' AND FASTAT='' THEN RESULT=FASTRESC;*/
/*   ELSE PUT "WARN" "ING: Check Device_B for results";*/
/**/
/*   DROP FASTRESC FASTAT;*/
/*RUN;*/

/*PROC TRANSPOSE DATA=DEVICE_C OUT=DEVICE_D(DROP=_NAME_);*/
/*   BY USUBJID FADTC;*/ /*22) JMH 13Jan2014*/
/*   VAR RESULT;*/
/*   ID FATESTCD;*/
/*   IDLABEL FATESTCD;*/
/*RUN;*/

* NICOTINE REPLACEMENT GUM TEST;
/*PROC SORT DATA=SDTM.FA(WHERE = (EPOCH='ADMI' AND FACAT='NICOTINE
REPLACEMENT THERAPY')) OUT=GUMTEST_B(KEEP =USUBJID) NODUPKEY;*/
/*   BY USUBJID;*/
/*RUN;*/
/*PROC SORT DATA=SDTM.FA(WHERE = ((EPOCH='ADMI' AND FATESTCD='NRTPERF')
OR (EPOCH='ADMI' AND FATESTCD='WILLABL' AND FACAT='NICOTINE REPLACEMENT
THERAPY')) ) */
/*   OUT=GUMTEST_B(KEEP =USUBJID FATESTCD FASTRESC FASTAT FADTC);*/
/*22) JMH 13Jan2014*/
/*   BY USUBJID;*/
/*RUN;*/
/**/
/*DATA GUMTEST_C;*/
/*   SET GUMTEST_B;*/
/*   ATTRIB RESULT FORMAT=$20.;*/
/**/
/*   IF FASTRESC='' AND FASTAT NE '' THEN RESULT=FASTAT;*/
/*   ELSE IF FASTRESC NE '' AND FASTAT='' THEN RESULT=FASTRESC;*/
/*   ELSE PUT "WARN" "ING: Check Gumtest_B for results";*/
/**/
/*   DROP FASTRESC FASTAT;*/
/*RUN;*/

/*PROC TRANSPOSE DATA=GUMTEST_C OUT=GUMTEST_D(DROP=_NAME_
rename=(willabl=nrtwill));*/
/*   BY USUBJID FADTC; *//*22) JMH 13Jan2014*/
/*   VAR RESULT;*/
/*   ID FATESTCD;*/
/*   IDLABEL FATESTCD;*/
/*RUN;*/

/*DATA DEVICE;*/
/*   MERGE DEVICE_A DEVICE_D*//*B*/*(IN=A);*/
/*   BY USUBJID;*/
/*   IF A;*/

/*   IF (PERFORM='NOT DONE'*/ /*OR PERFORM='No') OR (WILLABL='NOT DONE'
OR WILLABL='No'*//*) */

```

```

        /* THEN DELETE;*/ /* Remove the subjects with tests not done */
/*22) JMH 13Jan2014*/ /*25) JMH 14Jan2014*/

        /*DROP PERFORM *//*WILLABL*/;
/*RUN;*/
/*DATA GUMTEST;*/
/* MERGE GUMTEST_A GUMTEST_D*//*B*//*(IN=A);*/
/* BY USUBJID;*/
/* IF A;*/

        /* IF (NRTPERF='NOT DONE'*/ /*OR NRTPERF='No') OR (WILLABL='NOT DONE'
OR WILLABL='No'*//*)*/
/* THEN DELETE;*/ /* Remove the subjects with tests not done */ /*22)
JMH 13Jan2014*/ /*25) JMH 14Jan2014*/

        /*DROP NRTPERF *//*WILLABL*/ /*nrtwill*//*;*/
/*RUN;*/
/* 40) END KB 12Apr2014 */
/* 20) END KB 12Jan2014 */
/*18) END JMH 10Jan2014*/

data device2;
    set /*device*/DEVICE1A; /* 40) KB 12Apr2014 */
    /*IF DXSTDTC='' AND FADTC NE '' THEN DXSTDTC=FADTC;*//*22) JMH
13Jan2014*/ /* 40) KB 12Apr2014 */
    format dtestdtm /*datetime13.*/DATETIME16. dtestdt date9. dtesttm
/*time5.*/TIME8.; /* 40) KB 12Apr2014 */ /* 77) KB 08Aug2014 */
    if length(dxstdtc) gt 10 then do;
        /* dtestdtm = input(dxstdtc,e8601dt.);*/
        DTESTDTM =
DHMS(INPUT(SCAN(DXSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(DXSTDTC,2,'T'),
/*TIME5.*/TIME8.)),MINUTE(INPUT(SCAN(DXSTDTC,2,'T'),/*TIME5.*/TIME8.)),/*
0*/SECOND(INPUT(SCAN(DXSTDTC,2,'T'),TIME8.))); /* 66) KB 04Aug2014 */ /*
78) KB 21Sep2014 */
        dtesttm = timepart(dtestdtm);
        dtestdt = datepart(dtestdtm);
    end;
    else if not missing(dxstdtc) then dtestdt =
input(scan(dxstdtc,1,'T'),yyymmdd10.);
    drop dxstdtc /*FADTC*/; /*22) JMH 13Jan2014*/ /* 40) KB 12Apr2014
*/
run;

data gumtest2;
    set gumtest;
    /*IF EXSTDTC='' AND FADTC NE '' THEN EXSTDTC=FADTC;*//*22) JMH
13Jan2014*/ /* 40) KB 12Apr2014 */
    format ptestdtm /*datetime13.*/DATETIME16. ptestdt date9. ptesttm
/*time5.*/TIME8.; /* 40) KB 12Apr2014 */ /* 77) KB 08Aug2014 */
    if length(exstdtc) gt 10 then do;
        /* ptestdtm = input(exstdtc,e8601dt.);*/
        PTESTDTM =
DHMS(INPUT(SCAN(EXSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(EXSTDTC,2,'T'),
/*TIME5.*/TIME8.)),MINUTE(INPUT(SCAN(EXSTDTC,2,'T'),/*TIME5.*/TIME8.)),/*

```

```

0*/SECOND(INPUT(SCAN(EXSTDTC,2,'T'),TIME8.))); /* 66) KB 04Aug2014 */ /*
78) KB 21Sep2014 */
        ptesttm      = timepart(ptestdtm);
        ptestdt      = datepart(ptestdtm);
    end;
    else if not missing(exstdtc) then ptestdt =
input(scan(exstdtc,1,/*'t'*/'T'),yymmdd10.); /* 79) KB 21Sep2014 */
        drop exstdtc /*FADTC*/; /*22) JMH 13Jan2014*/ /* 40) KB 12Apr2014
*/
run;

/* 41) START KB 12Apr2014 */
DATA PERF;
    SET SDTM.FA(WHERE=(FATESTCD IN ('PERFORM' 'NRTPERF')));

    KEEP USUBJID FAORRES FATESTCD;
RUN;

PROC TRANSPOSE DATA=PERF OUT=PERF2(DROP=_:);
    BY USUBJID;
    VAR FAORRES;
    ID FATESTCD;
RUN;

DATA PERF3;
    SET PERF2;

    IF PERFORM NE 'Yes' AND NRTPERF NE 'Yes' THEN DELETE;

    KEEP USUBJID;
RUN;
/* 41) END KB 12Apr2014 */

data enr;
    merge /*sdtm.ds(where = (dscat = 'DISPOSITION EVENT' and dsterm =
'DISCONTINUED FROM ENROLLMENT') in = a)*/ /* 42) KB 12Apr2014 */
        alllds ie(in=b) device2/*(in=c)*/ gumtest2/*(in=d)*/
PERF3(IN=C); /* 41) KB 12Apr2014 */
    by usubjid;
    format enrlfl scrffl $2. ENFL EXFL EXNOTRFL $2.; /* 41) KB
12Apr2014 */ /* 60) KB 04Aug2014 */
    if /*a or */b or not c /*or not d*/ /*OR (C AND WILLABL IN ("No"
"NOT DONE")) OR (D AND NRTWILL IN ("No" "NOT DONE"))*/ then enrlfl =
'N'; * discontinued, invalid inclusion or exclusion or no valid device
test; /* 27) KB 14Jan2014 */ /* 40) KB 12Apr2014 */ /* 45) KB
12Apr2014 */ /* 42) KB 12Apr2014 */
        else enrlfl = 'Y'; * enrolled flag - all IE critieria not met at
admission or screening;

    if enrlfl='Y' then scrffl='N';
    else if enrlfl='N' then scrffl='Y';

/* 41) START KB 12Apr2014 */
    IF NOT C THEN EXFL='N';

```

```

ELSE EXFL='Y';
IF B THEN ENFL='N';
ELSE ENFL='Y';

IF ENFL='Y' THEN EXFL='N';
IF SCRFFL='Y' THEN DO;
    EXFL='N';
    ENFL='N';
END;
/* 41) END KB 12Apr2014 */

IF NOT C THEN EXNOTRFL = "N"; /* 60) KB 04Aug2014 */
ELSE EXNOTRFL = "Y"; /* 60) KB 04Aug2014 */

keep usubjid enrfl scrffl dtestdtm dtesttm dtestdt ptestdtm
ptesttm ptestdt ENFL EXFL EXNOTRFL; /* 41) KB 12Apr2014 */ /* 60) KB
04Aug2014 */
run;

* completion details;
data suplds;
    set sdtm.suplds(where=(qnam = 'OTHER'));
    dsseq = input(idvarval,best.);
    format dsreasp $200.;
    dsreasp = trim(propcase(qval,'/'));
    keep usubjid dsseq dsreasp;
run;

/* 39) START KB 12Apr2014 */
DATA SUPPDS2;
    MERGE SUPPDS(IN=A) SDTM.DS;
    BY USUBJID DSSEQ;
    IF A;
RUN;

PROC SORT DATA=SUPPDS2(WHERE=(DSCAT='DISPOSITION EVENT'));
    BY USUBJID DSSTDTC;
RUN;

DATA SUPPDS3;
    SET SUPPDS2;
    BY USUBJID DSSTDTC;

    IF FIRST.USUBJID AND FIRST.DSSTDTC THEN OUTPUT;
RUN;

DATA DSTEST2;
    SET SDTM.DS(WHERE = (DSCAT = 'DISPOSITION EVENT')) ;
RUN;

PROC SORT DATA=DSTEST2;
    BY USUBJID DSSTDTC;
RUN;

```

```

DATA DSTEST3;
    SET DSTEST2;
    BY USUBJID DSSTDTC;

    IF FIRST.USUBJID THEN OUTPUT;
RUN;

PROC SORT DATA=DSTEST3;
    BY USUBJID DSSEQ;
RUN;
/* 39) END KB 12Apr2014 */

data compa lastobs(/*where =(dscat = 'DISPOSITION EVENT')*/ keep =
usubjid dsdecod dscat epoch rename = (dsdecod = extrads)); /* 39) KB
12Apr2014 */
    merge /*sdtm.ds*/DSTEST3 /*suppds*/SUPPDS3; /* 39) KB 12Apr2014 */
    by usubjid dsseq;
    if last.usubjid then output lastobs; * final followup;
    output compa;
run;

data comp;
    merge compa(where = (dscat = 'DISPOSITION EVENT'))
           allds lastobs(drop = dscat)
SDTM.DS(WHERE=(FUEPOCH="FOLLOWUP") KEEP = USUBJID EPOCH RENAME=(EPOCH =
FUEPOCH) IN=FU); /* 65) KB 04Aug2014 */
    by usubjid;
    if first.usubjid;
    format complfl fupfl $2. discdt date9. dsreas dsreasp $200.;
    if dsterm = 'COMPLETED' then complfl = 'Y'; * completion of study
- all parts;
    else complfl = 'N';
    if dscat='DISPOSITION EVENT' and dsterm='LOST TO FOLLOW-UP' then
fupfl='N'; * completion of follow-up;
    /*else if epoch='FOLLOWUP'*/ ELSE IF FU then fupfl='Y'; /* 65) KB
04Aug2014 */
    /*else if epoch ne 'FOLLOWUP'*/ ELSE IF NOT FU then fupfl='N'; /*
65) KB 04Aug2014 */
    * date of completion\discontinuation;
    discdt = input(dsstdtc, yymmdd10.);
    *reason for discontinuation;
    if dsdecod='SCREEN FAILURE' then dsreas =
trim(propcase(dsterm, '/'));
    else if dsdecod ne 'COMPLETED' then dsreas =
trim(propcase(dsterm, '/'));
    if dsterm ne extrads and dsdecod ne 'SCREEN FAILURE' then dsreasp =
trim(propcase(extrads, '/'));
    keep usubjid complfl fupfl discdt dsreas; ;
run;
* randomisation details ;
data rand(keep = usubjid rand:);
    merge sdtm.ds(where = (dscat = 'PROTOCOL MILESTONE' and dsdecod =
'RANDOMIZED') in = a)
           allds;

```

```

        by usubjid;
        format randfl $2. randdtm datetime13. randdt date9.;
        if a then randfl = 'Y';
        else randfl = 'N';
        if randfl='Y' then do;
/*          randdtm = input(dsstdtc,e8601dt.);*/
          RANDDTM =
DHMS(INPUT(SCAN(DSSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(DSSTDTC,2,'T'),
TIME5.)),MINUTE(INPUT(SCAN(DSSTDTC,2,'T'),TIME5.)),0); /* 66) KB
04Aug2014 */
          randdt = datepart(randdtm);
        end;
run;
* combine flags ;
data flag;
    merge enr infcons comp rand;
    by usubjid;
run;

*****;
* add to DM5 ;
*****;

data dm6;
    merge dm5(in = a) flag(in = b);
    by usubjid;
    * subject not in DS data;
    if a and not b and not missing(armcd) then put 'USER WARN' 'ING
flagging data not available: ' usubjid=;
    format icfday dtestday ptestday 8. /*enfl exfl $2.*; /* 41) KB
12Apr2014 */
    icfday=icfdt - trtsdt + 1;
    * flag if enrolled but not randomised ;
/*    if enrfl = 'Y' and randfl = 'N' then enfl = 'Y';*/ /* 41) KB
12Apr2014 */
/*    else enfl = 'N';*/ /* 41) KB 12Apr2014 */
    * flag if exposed but not randomised ;
    /*if not missing(dtestdt) AND NOT MISSING(PTESTDT) and randfl = 'N'
then exfl = 'Y';*/ /*7) JMH 09Jan2014*/
    /*IF (NOT MISSING(DTESTDT) OR NOT MISSING(PTESTDT)) AND RANDFL =
'N' THEN EXFL = 'Y'; *//*13) JMH 10Jan2014*/ /* 41) KB 12Apr2014 */
/*    else exfl = 'N'; */ /* 41) KB 12Apr2014 */

    IF RANDFL='Y' AND ENFL='Y' THEN ENFL='N'; /* 41) KB 12Apr2014 */
    IF RANDFL='Y' AND ENRLFL='N' THEN ENRLFL='Y'; /* 59) KB 04Aug2014 */
    IF RANDFL = "Y" AND EXNOTRFL = "Y" THEN EXNOTRFL = "N"; /* 60) KB
04Aug2014 */

    dtestday = dtestdt - trtsdt + 1;
    ptestday = ptestdt - trtsdt + 1;

run;

```

```

proc sort data=sdtm.ex(where=(excat='NICOTINE REPLACEMENT THERAPY' /*AND
NOT MISSING(EXSTDTC)*/ /*and exstdy ge 1*/AND EPOCH='ADMI')) /*6) JMH
09Jan2014*/ /*15) JMH 10Jan2014*/ /* 52) KB 12Apr2014 */
    out=sfnrt(keep = usubjid);
    by usubjid;
run;

* safety flagging ;
data dm6a;
    merge dm6 device2(in=device) sfnrt(in=sfnrt); * trial period ;
    by usubjid;
    format saffl $2. safreas /*$40.*/$50.; /* 26) KB 14Jan2014 */
    if not missing(icfdt) and (device or SFNRT) then saffl = 'Y';
    else saffl = 'N';
    if saffl = 'N' then do;
        if not missing(icfdt) and not (device or sfnrt) then safreas =
/*'No exposure to THS 2.2 menthol or NRT Gum'*/ /*'No exposure to THS 2.2
or NRT GUM'*/'No exposure to THS 2.2 Menthol or NRT gum';/*24) JMH
14Jan2014*/ /* 53) KB 12Apr2014 */
        else if missing(icfdtc) then safreas = 'No informed consent';
        else if not missing(icfdtc) and not device then safreas =/*'No
exposure to THS 2.2 menthol'*/ /*'No exposure to THS 2.2'*/'No exposure
to THS 2.2 Menthol'; /*24) JMH 14Jan2014*/ /* 53) KB 12Apr2014 */
        else if not missing(icfdtc) and not SFNRT/*sfns*/ then safreas =
/*'No exposure to NRT Gum'*//*'No exposure to NRT GUM'*/'No exposure to
NRT gum';/*6) JMH 09Jan2014*/ /*24) JMH 14Jan2014*/ /* 53) KB 12Apr2014
*/
    end;
run;

* treatments;
data dm6b;
    set dm6a;
    format trt01pn trt02pn trt01an trt02an 8. trt01p trt02p trt01a
trt02a $40.;

    * planned treatments;
if randfl = 'Y' then do; * randomised subjects ;
    if armcd = 'THS 2.2M - MCC' then do;
        trt01pn = 4/*1*/; /*14) JMH 10Jan2014*/
        TRT01P = 'THS 2.2 Menthol'; /*23) JMH 13Jan2014*/
        /*TRT01P = 'THS 2.2M';*/ /*16) JMH 10Jan2014*/
        trt02pn = 5/*2*/; /*3) JMH 09Jan2014*/
        TRT02P = 'mCC' /*'MCC'*/; /*23) JMH 13Jan2014*/
    end;
else if armcd = 'MCC - THS 2.2M' then do;
        trt01pn = 5/*2*/; /*3) JMH 09Jan2014*/
        TRT01P = 'mCC' /*'MCC'*/; /*23) JMH 13Jan2014*/
        trt02pn = 4/*1*/; /*14) JMH 10Jan2014*/
        TRT02P = 'THS 2.2 Menthol'; /*23) JMH 13Jan2014*/
        /*TRT02P = 'THS 2.2M';*/ /*16) JMH 10Jan2014*/
    end;
else if armcd = 'THS 2.2M - NRT GUM' then do;
        trt01pn = 4/*1*/; /*14) JMH 10Jan2014*/

```



```

        TRT01P = 'THS 2.2 Menthol'; /*23) JMH 13Jan2014*/
        /*TRT01P = 'THS 2.2M';*/ /*16) JMH 10Jan2014*/
        trt02pn = 7/*6*/; /*14) JMH 10Jan2014*/
        trt02p = /*'NRT Gum'/'NRT gum'; /* 49) KB 12Apr2014 */
    end;
    else if armcd = 'NRT GUM - THS 2.2M' then do;
        trt01pn = 7/*6*/; /*14) JMH 10Jan2014*/
        trt01p = /*'NRT Gum'/'NRT gum'; /* 49) KB 12Apr2014 */
        trt02pn = 4/*1*/; /*14) JMH 10Jan2014*/
        TRT02P = 'THS 2.2 Menthol';/*23) JMH 13Jan2014*/
        /*TRT02P = 'THS 2.2M';*/ /*16) JMH 10Jan2014*/
    end;
    ELSE PUT "WA" "RNING: Unexpected ARMCD, please check " SUBJID=
    ARMCD=; /*10) JMH 10Jan2014*/
end;

    else if enfl = 'Y' then do;
        trt01pn = 97;
        trt01p = 'Enrolled not randomized';
        trt02pn = 97;
        trt02p = 'Enrolled not randomized';
    end;
    else if exfl = 'Y' then do;
        trt01pn = 98;
        trt01p = 'Exposed not randomized';
        trt02pn = 98;
        trt02p = 'Exposed not randomized';
    end;
    else if armcd = 'SCRNFAIL' then do;
        trt01pn = 99;
        trt01p = 'Screen failure';
        trt02pn = 99;
        trt02p = 'Screen failure';
    end;
    ELSE PUT "WA" "RNING: Unexpected ARMCD, please check " SUBJID=
    ARMCD=; /*1) JMH 09Jan2014*/
    * actual treatments ;
    if enfl='Y' then do;
        trt01an = 97;
        trt01a = 'Enrolled not randomized';
        trt02an = 97;
        trt02a = 'Enrolled not randomized';
    end;
    else if exfl = 'Y' then do;
        trt01an = 98;
        trt01a = 'Exposed not randomized';
        trt02an = 98;
        trt02a = 'Exposed not randomized';
    end;
    else if armcd='SCRNFAIL' then do;
        trt01an = 99;
        trt01a = 'Screen failure';
        trt02an = 99;
        trt02a = 'Screen failure';
    end;
end;

```

```

run;

proc sort data=sdtm.ex(where=(excat in ('MENTHOL CONVENTIONAL CIGARETTES'
'NICOTINE REPLACEMENT THERAPY') and exstdy gt -1 ))
    out=extrts(keep = usubjid excat visit);
    by usubjid;
run;

proc sort data=sdtm.dx(where=(excat in ('TOBACCO HEATING SYSTEM MENTHOL')
and dxstdy gt -1 ) rename=(dxcat=excat))
    out=dxtrts(keep = usubjid excat visit);
    by usubjid;
run;

data treatments;
    set extrts dxtrts;
run;

proc sort data=treatments;
    by usubjid visit;
run;

proc transpose data=treatments out=treatments02(drop=_name_ _label_);
    by usubjid;
    var excat;
    id visit;
    idlabel visit;
run;

data treatments03;
    merge dm6b treatments02;
    by usubjid;
        day_1=left(trim(day_1));
        day_3=left(trim(day_3));
run;

data dm6ba;
    set treatments03;
    if day_1 ne '' then do;
        if day_1='MENTHOL CONVENTIONAL CIGARETTES' then do;
            trt01an=5;
            trt01a='mCC' /*'MCC'*/; /*23) JMH 13Jan2014*/
        end;
        else if day_1='TOBACCO HEATING SYSTEM MENTHOL' then do;
            trt01an=4;
            TRT01A='THS 2.2 Menthol'; /*23) JMH 13Jan2014*/
            /*TRT01A='THS 2.2M';*/ /*16) JMH 10Jan2014*/
        end;
        else if day_1='NICOTINE REPLACEMENT THERAPY' then do;
            trt01an=7/*6*/; /*8) JMH 10Jan2014*/;
            trt01a='NRT Gum'/'NRT gum'; /* 49) KB 12Apr2014 */
        end;
        else put "warn" "ing: check subjects actual treatments for period
1" usubjid=;

```

```

end;
if day_3 ne '' then do;
    if day_3 = 'MENTHOL CONVENTIONAL CIGARETTES' then do;
        trt02an=5;
        trt02a='mCC' /*'MCC'*/; /*23) JMH 13Jan2014*/
    end;
    else if day_3='TOBACCO HEATING SYSTEM MENTHOL' then do;
        trt02an=4;
        TRT02A='THS 2.2 Menthol'; /*23) JMH 13Jan2014*/
        /*TRT02A='THS 2.2M';*//*16) JMH 10Jan2014*/
    end;
    else if day_3='NICOTINE REPLACEMENT THERAPY' then do;
        trt02an=7/*6*/; /*8) JMH 10Jan2014*/
        trt02a='/*'NRT Gum'*/'NRT gum'; /* 49) KB 12Apr2014 */
    end;
    else put "WARN" "ING: check subjects actual treatments for period
2" usubjid=;
    end;
    drop day_1 day_3;
run;

data dm6c;
    set dm6ba;
/*    length trtsega $200 trtseqp $200 analgr1 $10;*/ /* 54) KB 15Apr2014
*/
    format trtsegan 8. trtseqpn 8. analgr1n 8. TRTSEQA TRTSEQP $200.
ANALGR1 $10.; /* 54) KB 15Apr2014 */

/* 37) START KB 12Apr2014 */
    IF INDEX(DSREAS,'Withdr') THEN DO;
        IF TRT01A='' THEN TRTSEQA=TRIM(LEFT(COMPBL(TRT01P|| ' ' || '-' ||
' ' || TRT02A)));
        IF TRT02A='' THEN TRTSEQA=TRIM(LEFT(COMPBL(TRT01A|| ' ' || '-' ||
' ' || TRT02P)));
    END;
/* 37) END KB 12Apr2014 */

/* Deriving trtsega*/
if (trt01a ne 'Screen failure' and trt02a ne 'Screen failure') and
(trt01a ne '' and trt02a ne '') then do;
    trtsega = trim(left(compbl(trt01a || ' ' || '-' || ' ' ||
trt02a)));
/*Derive trtsega and trtsegan for enrolled not randomized and
exposed not randomised*/
    if trt01a=trt02a then trtsega=trt01a;
/*    if trt01an=97 then trtsegan=5;*/ /* 51) KB 12Apr2014 */
/*    else if trt01an=98 then trtsegan=6;*/ /* 51) KB 12Apr2014 */
end;
/*ELSE IF MISSING(TRT02A) AND NOT MISSING(TRT01A) THEN TRTSEQA =
TRIM(LEFT(COMPBL(TRT01A || ' ' || '-' || ' ' || TRT02P)));*//*10) JMH
10Jan2014*/ /* 37) KB 12Apr2014 */

/* Deriving trtsegan */

```

```

        IF TRTSEQA='THS 2.2 Menthol - mCC' THEN TRTSEQAN=1;          /*23) JMH
13Jan2014*/
        ELSE IF TRTSEQA='mCC - THS 2.2 Menthol' THEN TRTSEQAN=2; /*23) JMH
13Jan2014*/
        ELSE IF TRTSEQA=/'THS 2.2 Menthol - NRT Gum'/'THS 2.2 Menthol -
NRT gum' THEN TRTSEQAN=3; /*23) JMH 13Jan2014*/ /* 49) KB 12Apr2014 */
        ELSE IF TRTSEQA=/'NRT Gum - THS 2.2 Menthol'/'NRT gum - THS 2.2
Menthol' THEN TRTSEQAN=4; /*23) JMH 13Jan2014*/ /* 49) KB 12Apr2014 */
        /*IF TRTSEQA='THS 2.2M - MCC' THEN TRTSEQAN=1;*/ /*16) JMH
10Jan2014*/
        /*ELSE IF TRTSEQA='MCC - THS 2.2M' THEN TRTSEQAN=2;*/ /*16) JMH
10Jan2014*/
        /*ELSE IF TRTSEQA='THS 2.2M - NRT Gum' THEN TRTSEQAN=3;*/ /*16) JMH
10Jan2014*/
        /*ELSE IF TRTSEQA='NRT Gum - THS 2.2M' THEN TRTSEQAN=4;*/ /*16) JMH
10Jan2014*/
        ELSE IF TRTSEQA='Enrolled not randomized' THEN TRTSEQAN=5; /* 51) KB
12Apr2014 */
        ELSE IF TRTSEQA='Exposed not randomized' THEN TRTSEQAN=6; /* 51) KB
12Apr2014 */
/*      ELSE IF ARMCD='SCRNFAIL' THEN TRTSEQA='';*/ /* 64) KB 04Aug2014 */
        /*ELSE PUT "WA" "RNING: Unexpected trtseqa: " SUBJID= TRTSEQA;*/
/*9) JMH 10Jan2014*/ /* 51) KB 12Apr2014 */

        /* Deriving trtseqp */
        if /*arm*/ARMCD='THS 2.2M - MCC' then trtseqp=/'THS 2.2M - MCC'/'
'THS 2.2 Menthol - mCC'; /*23) JMH 13Jan2014*/ /* 50) KB 12Apr2014 */
        else if armcd='MCC - THS 2.2M' Then trtseqp=/'MCC - THS 2.2M'/'
'mCC - THS 2.2 Menthol';/*23) JMH 13Jan2014*/
        else if armcd='THS 2.2M - NRT GUM' then trtseqp=/'THS 2.2M - NRT
Gum'/'/'THS 2.2 Menthol - NRT Gum'/'THS 2.2 Menthol - NRT gum';/*23)
JMH 13Jan2014*/ /* 49) KB 12Apr2014 */
        else if armcd='NRT GUM - THS 2.2M' then trtseqp=/'NRT Gum - THS
2.2M'/'/'NRT Gum - THS 2.2 Menthol'/'NRT gum - THS 2.2 Menthol';/*23)
JMH 13Jan2014*/ /* 49) KB 12Apr2014 */
/*      ELSE IF ARMCD='SCRNFAIL' THEN TRTSEQP='';*/ /* 64) KB 04Aug2014 */
/*      ELSE PUT "WA" "RNING: Unexpected armcd: " SUBJID= ARMCD; *//*9)
JMH 10Jan2014*/ /* 51) KB 12Apr2014 */

        /* Deriving trtseqpn */
        if trtseqp=/'THS 2.2M - MCC'/' 'THS 2.2 Menthol - mCC' then
trtseqpn=1; /*23) JMH 13Jan2014*/
        else if trtseqp=/'MCC - THS 2.2M'/' 'mCC - THS 2.2 Menthol' then
trtseqpn=2; /*23) JMH 13Jan2014*/
        else if trtseqp=/'THS 2.2M - NRT Gum'/'/'THS 2.2 Menthol - NRT
Gum'/'/'THS 2.2 Menthol - NRT gum' then trtseqpn=3; /*23) JMH 13Jan2014*/
/* 49) KB 12Apr2014 */
        else if trtseqp=/'NRT Gum - THS 2.2M'/'/'NRT Gum - THS 2.2
Menthol'/'/'NRT gum - THS 2.2 Menthol' then trtseqpn=4; /*23) JMH
13Jan2014*/ /* 49) KB 12Apr2014 */
/*      ELSE IF ARMCD='SCRNFAIL' THEN TRTSEQPN='';*/ /* 64) KB 04Aug2014 */
/*      ELSE PUT "WA" "RNING: Unexpected trtseqp: " SUBJID= TRTSEQP;
*//*9) JMH 10Jan2014*/ /* 51) KB 12Apr2014 */

```

```

/* 64) START KB 04Aug2014 */
/* 51) START KB 12Apr2014 */
/* IF TRT01A='' AND TRT02A NE '' THEN DO;*/
/* TRTSEQA=TRTSEQP;*/
/* TRTSEQAN=TRTSEQPN;*/
/* END;*/
/* ELSE IF TRT01A NE '' AND TRT02A EQ '' THEN DO;*/
/* TRTSEQA=TRTSEQP;*/
/* TRTSEQAN=TRTSEQPN;*/
/* END;*/
/* 51) END KB 12Apr2014 */
/* 64) END KB 04Aug2014 */

/* Deriving analgr1 & analgrln */
if trtseqan in (1 2) then do;
    analgr1='Group-1';
    analgrln=1;
end;
else if trtseqan in (3 4) then do;
    analgr1='Group-2';
    analgrln=2;
end;
/* 51) START KB 12Apr2014 */
/* ELSE IF ARMCD='SCRNFAIL' THEN DO;*/
/* ANALGR1='';*/
/* ANALGR1N='';*/
/* END;*/
/* 51) END KB 12Apr2014 */
/*ELSE PUT "WA" "RNING: Unexpected trtseqan: " SUBJID= TRTSEQAN=;*/
/*9) JMH 10Jan2014*/ /* 51) KB 12Apr2014 */

IF /*ARMCD NE 'SCRNFAIL'*/TRTSEQA NOT IN ('' 'Enrolled not
randomized' 'Exposed not randomized') THEN DO; /*9) JMH 10Jan2014*/ /*
51) KB 12Apr2014 */
    IF TRTSEQA NE TRTSEQP THEN PUT "WA" "RNING: TRTSEQA and
TRTSEQP are different, please check " SUBJID= TRTSEQA= TRTSEQP=;
    IF TRTSEQAN NE TRTSEQPN THEN PUT "WA" "RNING: TRTSEQAN
and TRTSEQPN are different, please check " SUBJID= TRTSEQAN= TRTSEQPN=;
/*9) JMH 10Jan2014*/
    END;
run;

/* Keeping randomised subjects */
data random;
    set dm6c;
    where randfl='Y';

    keep usubjid;
run;

proc sort data=sdtm.ex(where=(visit ne 'DAY -1')) out=excomp(keep=usubjid
excat visit);
    by usubjid visit;
run;

```

```

data exrandom;
    merge random(in=a) excomp;
    by usubjid;
    LENGTH VISIT2 $15; /* 69) KB 04Aug2014 */

    if excat='' and visit='' then delete;

/* 69) START KB 04Aug2014 */
    VISIT2=VISIT;
    DROP VISIT;
    RENAME VISIT2=VISIT;
/* 69) END KB 04Aug2014 */
run;

proc sort data=sdtm.dx(where=(visit ne 'DAY -1')) out=dxcomp(keep=usubjid
dxcat visit rename=(dxcat=excat));
    by usubjid visit;
run;

data dxrandom;
    merge random(in=a) dxcomp;
    by usubjid;
    LENGTH VISIT2 $15; /* 69) KB 04Aug2014 */

    if excat='' and visit='' then delete;

/* 69) START KB 04Aug2014 */
    VISIT2=VISIT;
    DROP VISIT;
    RENAME VISIT2=VISIT;
/* 69) END KB 04Aug2014 */
run;

proc sort data=sdtm.lb(where=(lbtestcd='CO' and (visit ne 'DAY -1' and
visit ne /*'DISCHARGE CONFINEMENT'*//*'Day 4'*/'DAY 4/DISCHARGE'))
out=lbcomp(keep=usubjid lbstresn visit); /* 52) KB 12Apr2014 */ /* 74)
KB 06Aug2014 */
    by usubjid visit;
run;

/* Creating compliance flags */
data compflgs;
    merge exrandom dxrandom lbcomp;
    by usubjid visit;

    /*length*/FORMAT compl0fl compl1fl compl2fl compl3fl $2.; /* 55) KB
22Apr2014 */

/* 28) START KB 15Jan2014 */
/* IF NOT MISSING(LBSTRESN) THEN DO;*/ /* 74) KB 06Aug2014 */
    if visit='DAY 0' then do;

```

```

        if /*excat*//*=*/ /*IN ('MENTHOL CONVENTIONAL CIGARETTES'
'TOBACCO HEATING SYSTEM MENTHOL' 'NICOTINE REPLACEMENT THERAPY')*/ /* 44)
KB 12Apr2014 */ /* 63) KB 04Aug2014 */
        /*or lbstresn>10*/(EXCAT NE "") then compl0fl='N'; /* 63) KB
04Aug2014 */
        else compl0fl='Y';
    end;
    else if visit='DAY 1' then do;
        if excat=/'NICOTINE REPLACEMENT GUM'/'NICOTINE REPLACEMENT
THERAPY' then do; /* 45) KB 12Apr2014 */
            if lbstresn>10 then compl1fl='N';
            ELSE COMPL1FL='Y'; /* 56) KB 22Apr2014 */
        end;
        else compl1fl='Y';
    end;
    else if visit='DAY 2' then do;
        if /*excat*//*=*/ /*IN ('MENTHOL CONVENTIONAL CIGARETTES'
'TOBACCO HEATING SYSTEM MENTHOL' 'NICOTINE REPLACEMENT THERAPY')*/ /* 44)
KB 12Apr2014 */ /* 63) KB 04Aug2014 */
        (EXCAT NE "") or lbstresn>10 then compl2fl='N'; /* 63) KB
04Aug2014 */
        else compl2fl='Y';
    end;
    else if visit='DAY 3' then do;
        if excat=/'NICOTINE REPLACEMENT GUM'/'NICOTINE REPLACEMENT
THERAPY' then do; /* 45) KB 12Apr2014 */
            if lbstresn>10 then compl3fl='N';
            ELSE COMPL3FL='Y'; /* 56) KB 22Apr2014 */
        end;
        else compl3fl='Y';
    end;
/* END;*/ /* 74) KB 06Aug2014 */
/* 28) END KB 15Jan2014 */

```

```

    keep usubjid compl0fl compl1fl compl2fl compl3fl;

```

```

run;

```

```

proc sort data=compflgs out=compflgs2 nodupkey;
    by usubjid compl0fl compl1fl compl2fl compl3fl;
run;

```

```

data compflgs3;
    merge compflgs2(where=(not missing(compl0fl)) keep=usubjid
compl0fl) compflgs2(where=(not missing(compl1fl)) keep=usubjid compl1fl)
    compflgs2(where=(not missing(compl2fl)) keep=usubjid compl2fl)
    compflgs2(where=(not missing(compl3fl)) keep=usubjid compl3fl);
    by usubjid;

```

```

    if first.usubjid then sort=1;
run;

```

```

data compflgs4;
    set compflgs3(where=(sort=1));

```

```

        drop sort;
run;

data dm6d;
    merge dm6c(IN=A) compflgs4;
    by usubjid;
    IF A;
run;

*****;
* introduce SV data for dates of visits ;
*****;

data sv;
    set sdtm.sv;
    by usubjid;
    if last.usubjid;
    format lvisdt date9. lvisdtc $20. lvisit $40.;
    lvisdtc = trim(/*svstdtc*/SVENDTC); /* 73) KB 06Aug2014 */
    lvisdt = input(scan(lvisdtc,1,'T'),yymmdd10.);
    lvisit = trim(propcase(visit,'/'));
    keep usubjid lvis: ;
run;

*****;
* add to DM6d ;
*****;

data dm7;
    merge dm6d sv;
    by usubjid;
    format lvisday 8.;
    lvisday = lvisdt - trtsdt + 1;
run;

/* Deriving PPROTFL */
/* SAFFL & RANDFL = Y */
data pprotfl;
    set dm7(where=(saffl='Y' and randfl='Y'));
    keep usubjid saffl randfl;
run;

/* At least one of the single use days (EX or DX) */
data daycheck;
    merge sdtm.ex(where=(exstdy > 0) keep=usubjid exstdy)
    sdtm.dx(where=(dxstdy > 0) keep=usubjid dxstdy);
    by usubjid;
    day='Y';
    drop exstdy dxstdy;
run;

data pprotfl2;

```



```

        merge pprotfl1(in=a) daycheck(in=b);
        by usubjid;
        if a and b;
run;

/* Bringing in protocol deviations */
data devs;
    set sdtm.ie(where=(/*ietestcd in ('INC03' 'INC06' 'INC07' 'INC08'
'EXC01' 'EXC03' 'EXC16' 'EXC18')*/ /*or ietestcd not in ('EXC02'
'EXC17')*//*11) JMH 10Jan2014*/ /* 62) KB 04Aug2014 */
        (INDEX(IETESTCD,'INC')=1 AND IETESTCD NOT IN ('INC03' 'INC06' 'INC07'
'INC08')) OR (IETESTCD IN ('EXC02' 'EXC17' 'EXC19'))));/* 62) KB
04Aug2014 */

        if index(ietestcd,'EXC') and iestresc ne 'Y' then put "WARN" "ING:
Check IE SDTM for exclusion result";
        else if index(ietestcd,'INC') and iestresc ne 'N' then put "WARN"
"ING: Check IE SDTM for inclusion result";

        keep usubjid;
run;

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

data pprotfl3;
    merge pprotfl2(in=a) devs(in=b);
    by usubjid;
    if a and not b;
run;

/* Checking for banned medications in SDTM.CM */
proc import

datafile="/cvn/projects/prj/data/000000106326/source/bannedmeds.xlsx"
    out=work.medlist
    replace
    dbms=xlsx;
    range="A1:A68";
    getnames=no;
run;

proc sort data = medlist(rename = (a = check));
    by check;
run;
* no cm data;                                /*TEMP FIX!!*/
/*data cmmeds;
    set sdtm.cm(keep=usubjid cmtrt);

    check=lowercase(cmtrt);
run;

proc sort data=cmmeds;

```

```

        by check;
run;

data cmmeds2(drop = check);
    merge cmmeds(in = cm) medlist(in = list);
    by check;
    if cm;
    format crit1fl $2. crit1 $50.;
    crit1 = 'Affects CYP2A6';
    if cm and list then crit1fl = 'y';
    else crit1fl = 'N';
run;

proc sort data=cmmeds2;
    by usubjid;
run;*/

/*Checking use of NRT */
/* 46) START KB 12Apr2014 */
/*data nnsex;*/
/*    set sdtm.fa(where=(facat='NICOTINE REPLACEMENT GUM' and
epoch='ADMI')); */
/*    if exdose ne 1 then nrtfail='Y';*/
/*else*/ /*nrtfail='N';*/ /*Study Specific PK-05 Query being raised
as no data about how long gum was chewed for*/

/*    keep usubjid nrtfail;*/
/*run;*/
DATA NRTEX;
    SET SDTM.EX(WHERE=(EXCAT='NICOTINE REPLACEMENT THERAPY'));

    FORMAT EXSTDTM EXENDTM DATETIME16.;
    IF LENGTH(EXSTDTC) GT 10 THEN DO;
/*        EXSTDTM = INPUT(EXSTDTC,E8601DT.);*/
        EXSTDTM =
DHMS(INPUT(SCAN(EXSTDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(EXSTDTC,2,'T'),
TIME5.)),MINUTE(INPUT(SCAN(EXSTDTC,2,'T'),TIME5.)),0); /* 66) KB
04Aug2014 */
        END;
        IF LENGTH(EXENDTC) GT 10 THEN DO;
/*            EXENDTM = INPUT(EXENDTC,E8601DT.);*/
            EXENDTM =
DHMS(INPUT(SCAN(EXENDTC,1,'T'),YYMMDD10.),HOUR(INPUT(SCAN(EXENDTC,2,'T'),
TIME5.)),MINUTE(INPUT(SCAN(EXENDTC,2,'T'),TIME5.)),0); /* 66) KB
04Aug2014 */
            END;

            IF (EXENDTM - EXSTDTM) LT 10 THEN NRTFAIL='Y';
            ELSE NRTFAIL='N';

/*    KEEP USUBJID NRTFAIL;*/
RUN;
/* 46) END KB 12Apr2014 */

```

```

data pprotfl4;
    merge pprotfl3(in=a) /*nnsex*/NRTEX /*cmmeds2*/; /* 46) KB
12Apr2014 */
    by usubjid;
    if a;
    format pprotfl $2. ppreas $200.;

    /*if critlfl = '' then critlfl = 'N'; */

    if saffl='Y' and randfl='Y' and day='Y' /*and nrtfail='N'*//* and
critlfl='N'*/AND NRTFAIL='N' then pprotfl='Y'; /* 29) TEMPFIX Study
specific due to no times for NRT gum, uncomment nrtfail = 'N' when we
have data - KB 15Jan2014 */ /* 46) KB 12Apr2014 */
    else if saffl='N' | randfl='N' | day='N' | nrtfail='Y' /*|
critlfl='Y'*/ then pprotfl='N';
    else if nrtfail='Y' and saffl='Y' and day='Y' then ppreas='Use of
NRT gum for less than 10 min';
/* else if critlfl='Y' then ppreas='Use of medications known to affect
CYP2A6';*/

    keep usubjid pprotfl ppreas day nrtfail /*critlfl*/;
run;

/* 58) JH 16JUN2014 - START */
DATA PCDATA(WHERE=(NOT MISSING(PCFLAG)));
    SET SDTM.PC(WHERE=(PCSTAT NE 'NOT DONE' AND PCTESTCD='NIC'));
    IF INDEX(PCTPT,'24H') THEN PCFLAG=1;

    KEEP USUBJID PCGRPID PCFLAG PCTESTCD;
RUN;

PROC TRANSPOSE DATA=PCDATA OUT=PCDATA2(DROP=_NAME_);
    BY USUBJID PCTESTCD;
    VAR PCFLAG;
    ID PCGRPID;
RUN;

DATA PCDATA3;
    MERGE PPROTFL4 PCDATA2;
    BY USUBJID;
RUN;
/* 58) JH 16JUN2014 - END */

data dm8;
    merge dm7(in=a) PCDATA3/*pprotfl4*/; /* 58) JH 16JUN2014 */
    by usubjid;
    if a;
    format ppreas $200.;

    if saffl='N' then do;
        ppreas='Subject not in safety population';
        pprotfl='N';
    end;

```

```

/* 62) START KB 04Aug2014 */
/*   if pprotfl='' and day = '' then do;*/
/*       ppreas='No day 1 or day 3 data present';*/
/*       pprotfl='N'; *//* If day is missing then there is no day 1 or
day 3 data */
/*   end;*/
/* 62) END KB 04Aug2014 */

/*   else if pprotfl='' and nrtfail = '' then do;*/
/*       ppreas='No NRT test data present';*/
/*       pprotfl='N';*/ /*if nrtfail is missing then there is no NRT
test data*/
/*   end;*/

/* 29) TEMPFIX Study specific due to no times for NRT gum - KB 15Jan2014
*/
/* Setting PPROTFL and PPREAS to blank if subject randomized to NRT
gum */
/* Remove this when we have times for NRT gum */
/* 46) START KB 12Apr2014 */
/*   IF INDEX(TRTSEQA,'NRT') THEN DO;*/
/*       PPROTFL='';*/
/*       PPREAS='';*/
/*   END; */
/* 46) END KB 12Apr2014 */

/* 36) START KB 12Apr2014 */
/*   ELSE IF RANDFL='N' THEN DO; /* 71) KB 06Aug2014 */
/*       PPREAS='Subject not randomized';
/*       PPROTFL='N';
/*   END;
/* 36) END KB 12Apr2014 */
/*   IF SUBJIDN=107 THEN DO; /* 57) SM 04Jun2014 */
/*       PPROTFL='N';
/*       PPREAS='Did not complete at least one of the single use days'; *
CONSISTENT WITH PK-06;
/*   END;

/*   58) JH 16JUN2014 - START */
/*   IF (DAY_1=. AND DAY_3=.) AND PPROTFL='Y' THEN do;
/*       PPROTFL='N';
/*       PPREAS='Did not complete at least one of the single use days';
/*   END;
/*   58) JH 16JUN2014 - START */

drop icfdtc day nrtfail /*crit1fl*/ FATESTCD EPOCH /*WILLABL*/
TRTS1 TRTS2 PCTESTCD DAY_1 DAY_3; /*12) JMH 10Jan2014*/ /*30) JMH
15Jan2014*/ /* 48) KB 12Apr2014 */ /* 67) KB 04Aug2014 */

run;

/* 76) START KB 07Aug2014 */
DATA DM9;

```

```

SET DM8;

IF TRTSEQA='Enrolled not randomized' AND COMPL0FL='Y' THEN COMPL0FL='
';

IF RANDFL='Y' AND TRTSEQA NE TRTSEQP THEN PUT "USER WARN" "ING:
Subjects planned & actual treatment sequences do not match " USUBJID=
TRTSEQA= TRTSEQP=; /* 80) KB 21Sep2014 */
RUN;
/* 76) END KB 07Aug2014 */

*****;
* create output dataset ;
*****;

options replace;

data adsl;
    set stdlib.adsl /*dm8*/DM9;    /* 76) KB 07Aug2014 */
run;
proc sort data = adsl out = adam.adsl(label= 'Subject Level Analysis
Dataset') nodupkey;
    by usubjid;
run;

options noreplace;
%_scramble(set=adsl, id=USUBJID SUBJID SUBJIDN age ageu brthdt brthdtc
sex sexc sexn race racen raceoth ethnic ethnicn country dthfl height
weightbl bmi bmigr1 bmigrln ucpdgr1 ucpdgrln nicobl nicogr1 /*21) JMH
13Jan2014*/
        nicogrln tarbl targr1 targrln analgr1 analgrln,
dates=randdtm randdt trtsdtm trtsdt trtsday trtedtm trtedt trteday
tr01sdt tr01stm tr01sdm tr01edt tr01etm tr01edtm
        tr02sdt tr02stm tr02sdm tr02edt tr02etm tr02edtm,
nullc=DMRANDNO TRTSTMF TR01STMF TR02STMF dsreas dsreasp arm armcd trt01p
trt02p trt01a trt02a trtseqp trtseqa compl0fl compl1fl compl2fl compl3fl,
/* 47) KB 12Apr2014 */
        nulln=armcdn trt01pn trt02pn trt01an trt02an trtseqpn
trtseqan, nullcc=/*14*/18, nullnc=7); /* 47) KB 12Apr2014 */

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

```