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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 : 000000106324;
%put NOTE: Client Protocol ID : ZRHR-REXC-03-EU;
%put NOTE: Program Name : d_2ADLB.sas;
%put NOTE: Purpose : create ADLB dataset;
%put NOTE: ;
%put NOTE: Input Data : STDLIB.ADLB SDTM.LB SDTM.SUPPLB
ADAM.ADSL;
%put NOTE: Output : ADAM.ADLB;
%put NOTE: Macros Called : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by : cvn_smulholl;
%put NOTE: Creation Date : 2013-11-23;
%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: 30Nov2013 SM 1) Add WBC to ANL01FL;
%put NOTE: 2) Add in specific gravity for
PARAMN;
%put NOTE: 01May2014 KB 3) Removed format from LBSEQ;
%put NOTE: 01May2014 KB 4) Added categories to labs pull out;
%put NOTE: 01May2014 KB 5) Added derived parameters;
%put NOTE: 01May2014 KB 6) Removed code for unscheduleds;
%put NOTE: 01May2014 KB 7) Amended ABLFL;
%put NOTE: 01May2014 KB 8) Added PARCAT1 to merge;
%put NOTE: 01May2014 KB 9) Excluded biomarker data;
%put NOTE: 01May2014 KB 10) Added character results for HBSAG
and HCAB;
%put NOTE: 01May2014 KB 11) Amended ANRIND;
%put NOTE: 01May2014 KB 12) Amended ANL01FL;
%put NOTE: 01May2014 KB 13) Amended AEOSFL and EOS;
%put NOTE: 01May2014 KB 14) Amended sorting by key variables;
%put NOTE: 01May2014 KB 15) Removed SDTM variables for derived
parameters;
%put NOTE: 01May2014 KB 16) Added AQLFL and EPOCH to keep
statement;
%put NOTE: 01May2014 KB 17) Removed risk markers;
%put NOTE: 01May2014 KB 18) Amended ATOXGR derivation;
%put NOTE: 14May2014 KB 19) Added PARAMN for OCCBLD;

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%put NOTE: 14May2014	KB	20) Amended format of AVALC and added format to AVISITN;
%put NOTE: 14May2014	KB	21) Added pregnancy data;
%put NOTE: 14May2014	KB	22) Removed derivations of ALB K MCHC RBC SODIUM;
%put NOTE: 14May2014	KB	23) Amended HIV12AB as it is character;
%put NOTE: 14May2014	KB	24) Added SLBALL;
%put NOTE: 15May2014	KB	25) Rounded CHG;
%put NOTE: 15May2014	KB	26) Amended PARAM format;
%put NOTE: 15May2014	KB	27) Amended ABLFL;
%put NOTE: 15May2014	KB	28) Amended WBC issue;
%put NOTE: 15May2014	KB	29) Amended derived parameters;
%put NOTE: 15May2014	KB	30) Amended mapping for AVALC for derived parameters;
%put NOTE: 15May2014	KB	31) Amended AVAL for BLQ;
%put NOTE: 15May2014	KB	32) Added HIV12ABC to ANL01FL null;
%put NOTE: 15May2014	KB	33) Populated ANRLO and ANRHI for certain AVALCs;
%put NOTE: 15May2014	KB	34) Amended ABLFL for HIV data;
%put NOTE: 15May2014	KB	35) Added URBC to ANL01FL setting to blank;
%put NOTE: 15May2014	KB	36) Amended baselines;
%put NOTE: 16May2014	KB	37) Removed ABLFL for LBALLs;
%put NOTE: 16May2014	KB	38) Amended ANRLO derivation to remove condition for currently missing ANRLOs;
%put NOTE: 16May2014	KB	39) Amended baselines by adding AVISITN check;
%put NOTE: 16May2014	KB	40) Amended AEOSFL;
%put NOTE: 16May2014	KB	41) Amended update ANRLO to check for dashes in LBNSTRC;
%put NOTE: 16May2014	KB	42) Amended AVAL for > results;
%put NOTE: 04Jun2014	KB	43) Added ATPTN to key variables sort;
%put NOTE: 04Jun2014	KB	44) Amended ABLFL for some serology parameters;
%put NOTE: 05Jun2014	KB	45) Amended ABLFL for subject 10s unscheduled results;
%put NOTE: 27Jul2014	KB	46) Added EXNOTRFL;
%put NOTE: 28Jul2014	KB	48) updated SHIFT2, ATOXGR and BTOXGR bease on SDTM and other studies.;
%put NOTE: 13Sep2014	KB	49) Amended ABLFL;
%put NOTE: 13Sep2014	KB	50) Added ACLSIG;
%put NOTE: 13Sep2014	KB	51) Renamed datasteps to avoid overwriting;
%put NOTE: 13Sep2014	KB	52) Added clinical significance in to SHIFT1;
%put NOTE: 13Sep2014	KB	53) Amended lengths of variables in toxgrade for merging;
%put NOTE: 15Sep2014	KB	54) Amended ANL01FL for blan ATPT;
%put NOTE: 15Sep2014	KB	55) Removed the D from the PARAMCD for derived results;
%put NOTE: 21Oct2014	KB	56) Added toxicity to derived parameters;
%put NOTE: 23Oct2014	KB	57) Added AFASTFL;
%put NOTE: ;		

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%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

*=====;
* START OF PROGRAM CODE ;
*=====;
*****;
* bring in ADSL ;
*****;

data adsl;
    set adam.adsl;
    keep studyid usubjid subjid: siteid age sex: race height weightb1
bmi ucpdgr1 ucpdgrln nicogr1 nicogrln targr1 targrln cobl
        enrfl scrffl complfl saffl fasfl pprotfl randfl trt: trt01:
tr01: dthfl enfl EXNOTRFL exfl fupfl; /* 46) KB 27Jul2014 */
run;

*****;
* bring in SUPPLB ;
*****;

proc transpose data=sdtm.supplb out=supplb(drop = _:);
    var qval;
    by usubjid idvarval;
    id qnam;
    idlabel qlabel;
run;

data supplb2(drop = idvarval);
    set supplb;
/*    format lbseq 8.;*/ /* 3) KB 01May2014 */
    lbseq = input(idvarval, best.);
run;

proc sort data=supplb2;
    by usubjid lbseq;
run;

*****;
* bring in LB ;
*****;

*select relevant safety data only ;
*leave urine volume with biomarker data;
proc sort data = sdtm.lb out = /*lb*/LB1(where =
(INDEX(LBGRPID,'BIOMARKER')=0 AND lbcat in ('HAEMATOLOGY' 'CLINICAL
CHEMISTRY' 'SEROLOGY' 'URINALYSIS' 'COTININE SCREENING' 'ALCOHOL TEST'
'DRUG SCREEN' 'PREGNANCY') and lbtestcd /*ne*/NOT IN ('UVOL' 'PGF2A'

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'TXB2_D11'))); /* 4) KB 01May2014 */ /* 9) KB 01May2014 */ /* 17) KB
01May2014 */ /* 21) KB 14May2014 */ /* 51) KB 13Sep2014 */
    by usubjid lbseq;
run;

/* 48) JM 28JUL2014 start*/
PROC SORT DATA=SOURCE.TOXGRADE OUT=TOXGRADE;
    BY LBCAT LBSCAT LBNAM LBSPEC LBTESTCD LBTEST LBORRESU LBSTRESU;
    where lbcatt ne 'BIOMARKERS';
RUN;

/* 53) START KB 13Sep2014 */
DATA TOXGRADE2;
    SET TOXGRADE;
    LENGTH LBCAT2 $18 LBSCAT2 $22 LBTEST2 $39 LBORRES2 LBSTRES2 $7 LBNAM2
$8 LBSPEC2 $11;

    LBCAT2=LBCAT;
    LBSCAT2=LBSCAT;
    LBTEST2=LBTEST;
    LBORRES2=LBORRESU;
    LBSTRES2=LBSTRESU;
    LBNAM2=LBNAM;
    LBSPEC2=LBSPEC;

    RENAME LBCAT2=LBCAT LBSCAT2=LBSCAT LBTEST2=LBTEST LBORRES2=LBORRESU
LBSTRES2=LBSTRESU LBNAM2=LBNAM LBSPEC2=LBSPEC;
    DROP LBCAT LBSCAT LBTEST LBORRESU LBSTRESU LBNAM LBSPEC;
RUN;
/* 53) END KB 13Sep2014 */

PROC SORT DATA=/*LB*/LB1; /* 51) KB 13Sep2014 */
    BY LBCAT LBSCAT LBNAM LBSPEC LBTESTCD LBTEST LBORRESU LBSTRESU;
RUN;

DATA LB;
    MERGE /*LB*/LB1(IN=A) /*TOXGRADE*/TOXGRADE2(IN=B); /* 51) KB 13Sep2014
*/ /* 53) KB 13Sep2014 */
    BY LBCAT LBSCAT LBNAM LBSPEC LBTESTCD LBTEST LBORRESU LBSTRESU;
    IF A AND B THEN TOXFLAG=1;
RUN;
/* 48) JM 28JUL2014 end*/

/* 50) START KB 13Sep2014 */
PROC SORT DATA=LB;
    BY USUBJID LBSEQ;
RUN;

DATA LB2AB;
    MERGE LB(IN=A) SUPPLB2;
    BY USUBJID LBSEQ;
    IF A;
RUN;
/* 50) END KB 13Sep2014 */

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/* 5) START KB 01May2014 */
DATA LBDERIVED(WHERE=(LBTESTCD NE ''));
  SET /*LB*/LB2AB; /* 50) KB 13Sep2014 */
  LENGTH LBTESTCD2 $8 LBSTRESU2 $7;
  FORMAT PARAMTYP DTYPE $20. ACLSIG $3. AFASTFL $1.; /* 50) KB
13Sep2014 */ /* 57) KB 23Oct2014 */

  IF LBTESTCD IN ('BASO' 'PLAT' /*'WBC'*/ /*'ALB'*/ 'EOS' 'LYM' 'MONO'
'NEUT' /*'RBC' 'K' 'SODIUM' 'MCHC'*/) OR (LBTESTCD='WBC' AND
LBCAT='HAEMATOLOGY') THEN DO; /* 22) KB 14May2014 */ /* 28) KB 15May2014
*/
    LBTESTCD2=COMPRESS(/*'D' || */LBTESTCD); /* 55) KB 15Sep2014 */
    PARAMTYP='DERIVED';
    DTYPE='FUNCTION';
/* 22) START KB 14May2014 */
/*      IF LBTESTCD='ALB' THEN DO; */
/*          LBSTRESN2=LBSTRESN*10;*/
/*          LBSTRESC2=STRIP(PUT(LBSTRESN2,BEST.));*/
/*          LBSTRESU2='g/L';*/
/*          LBSTNRLO2=LBSTNRLO*10;*/
/*          LBSTNRHI2=LBSTNRHI*10;*/
/*      END;*/
/* 22) END KB 14May2014 */
/*ELSE*/ IF LBTESTCD='BASO' THEN DO; /* 22) KB 14May2014 */
    LBSTRESN2=LBSTRESN/*1000*/; /* 29) KB 15May2014 */
    LBSTRESC2=/*STRIP(PUT(LBSTRESN2,BEST.))*/LBSTRESC; /* 30) KB
15May2014 */
    LBSTRESU2='G/L';
    LBSTNRLO2=LBSTNRLO/*1000*/; /* 29) KB 15May2014 */
    LBSTNRHI2=LBSTNRHI/*1000*/; /* 29) KB 15May2014 */
    END;
    ELSE IF LBTESTCD IN ('EOS' 'LYM' 'MONO' 'NEUT' 'WBC') THEN DO;
    LBSTRESN2=LBSTRESN/*1000*/; /* 29) KB 15May2014 */
    LBSTRESC2=/*STRIP(PUT(LBSTRESN2,BEST.))*/LBSTRESC; /* 30) KB
15May2014 */
    LBSTRESU2='G/L';
    LBSTNRLO2=LBSTNRLO/*1000*/; /* 29) KB 15May2014 */
    LBSTNRHI2=LBSTNRHI/*1000*/; /* 29) KB 15May2014 */
    END;
    IF LBTESTCD='PLAT' THEN DO;
    LBSTRESN2=LBSTRESN/*10*/; /* 29) KB 15May2014 */
    LBSTRESC2=/*STRIP(PUT(LBSTRESN2,BEST.))*/LBSTRESC; /* 30) KB
15May2014 */
    LBSTRESU2='G/L';
    LBSTNRLO2=LBSTNRLO/*10*/; /* 29) KB 15May2014 */
    LBSTNRHI2=LBSTNRHI/*10*/; /* 29) KB 15May2014 */
    END;
/* 22) START KB 14May2014 */
/*      ELSE IF LBTESTCD='RBC' THEN DO;*/
/*          LBSTRESN2=LBSTRESN/100; */
/*          LBSTRESC2=STRIP(PUT(LBSTRESN2,BEST.)); */
/*          LBSTRESU2='T/L';*/
/*          LBSTNRLO2=LBSTNRLO/100;*/

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/*          LBSTNRHI2=LBSTNRHI/100;*/
/*      END;*/
/*      ELSE IF LBTESTCD IN ('K' 'SODIUM') THEN DO;*/
/*          IF LBORRES NE '-' THEN DO;*/
/*              LBSTRESN2=INPUT(LBORRES,BEST.);*/
/*              LBSTRESC2=STRIP(LBORRES); */
/*          END;*/
/*          ELSE DO;*/
/*              LBSTRESN2=.;*/
/*              LBSTRESC2=STRIP(LBORRES);*/
/*          END;*/
/*          LBSTRESU2=STRIP(LBSTRESU); */
/*          LBSTNRLO2=LBORNRL0; */
/*          LBSTNRHI2=LBORNRI; */
/*      END;*/
/*      ELSE IF LBTESTCD='MCHC' THEN DO;*/
/*          LBSTRESN2=LBSTRESN;*/
/*          LBSTRESC2=STRIP(LBSTRESC); */
/*          LBSTRESU2='g/dL';*/
/*          LBSTNRLO2=LBSTNRLO;*/
/*          LBSTNRHI2=LBSTNRHI;*/
/*      END;*/
/* 22) END KB 14May2014 */
END;
ACLSIG=LBCLSIG; /* 50) KB 13Sep2014 */
DFLAG=1; /* 55) KB 15Sep2014 */
LBTOXGR2=LBTOXGR ;/* 56) KB 21Oct2014 */
AFASTFL=LBFAST; /* 57) KB 23Oct2014 */

KEEP STUDYID USUBJID LBTEST LBCAT LBSCAT LBSTAT LBREASND VISITNUM
VISIT LBDTC LBTP T LBTPNUM LBTESTCD2 LBSTRESN2 LBSTRESC2 LBSTRESU2
LBSTNRLO2 LBSTNRHI2 PARAMTYP DTYPE LBNRIND ACLSIG DFLAG LBTOXGR2 TOXFLAG
AFASTFL; /* 50) KB 13Sep2014 */ /* 55) KB 15Sep2014 */ /* 56) KB
21Oct2014 */ /* 57) KB 23Oct2014 */
RENAME LBTESTCD2=LBTESTCD LBSTRESN2=LBSTRESN LBSTRESC2=LBSTRESC
LBSTRESU2=LBSTRESU LBSTNRLO2=LBSTNRLO LBSTNRHI2=LBSTNRHI
LBTOXGR2=LBTOXGR; /* 56) KB 21Oct2014 */
RUN;

DATA LBDERIVED2;
SET /*LB*/LB2AB LBDERIVED; /* 50) KB 13Sep2014 */
RUN;

PROC SORT DATA=LBDERIVED2;
BY USUBJID LBSEQ;
RUN;
/* 5) END KB 01May2014 */

* check parameters and units to SAP;
* all original and standardised units match so only keep 1 set of data ;
proc sort data = lb out=lbchk(keep = lbcat lbscat lbtestcd lbtest
lborresu lbstresu) nodupkey;
by lbcat lbscat lbtestcd lbtest lborresu lbstresu;
run;

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* check for unscheduled observations;
proc sort data = lb(where = (index(upcase(visit),'UNSCHEDULED')) out =
uns nodupkey;
    by usubjid visitnum visit lbtpt lbtptnum lbdtc;
run;

* combine with supplb ;
data lb2;
    /*merge*/SET /*lb*/LBDERIVED2(in = a) /*supplb2(drop = sampdtc
*//samtptim*//bactub prmtub)*//; * these are blank when merged with
safety labs; /* 5) KB 01May2014 */ /* 50) KB 13Sep2014 */
/*    by usubjid lbseq;*/ /* 50) KB 13Sep2014 */
/*    if a; */ * some may be biomarker data so exclude; /* 50) KB
13Sep2014 */

    format paramcd $8. parcat1 $40. avisit $40. paramn parcatln 8. aval
atptn AVISITN best. param /*$50.*/$60. /* 20) KB 14May2014 */ /* 26) KB
15May2014 */
    /*avalc*/ anrind anrlo anrhi atpt $50. AVALC $200. /* 20) KB
14May2014 */
    adt date9. adtm datetime13. atm time5. /*ablfl*/ bloqfl aulqfl
aqlfl $2. avalu atoxgr $20.; /* 49) KB 13Sep2014 */
    * parameter variables ;
    if lbcat = 'CLINICAL CHEMISTRY' then parcatln = 1;
    else if lbcat = 'HAEMATOLOGY' then parcatln = 2;
    else if lbcat = 'URINALYSIS' then do;
        if lbtestcd not in ('AMPHET' 'BARB' 'BNZDZPN' 'CANNAB'
'COCAINE' 'ETHANOL' 'OPIATE' 'PREGTEST') then parcatln = 3;
        else parcatln = 4;
    end;
    else if lbcat in ('COTININE SCREENING' 'SEROLOGY' 'PREGNANCY') then
parcatln = 4; /* 21) KB 14May2014 */
/* 4) START KB 01May2014 */
    ELSE IF LBCAT='ALCOHOL TEST' AND LBTESTCD='ETHANOL' THEN PARCAT1N=4;
    ELSE IF LBCAT='DRUG SCREEN' THEN PARCAT1N=4;
    ELSE IF LBCAT IN ('HBSAG' 'HCAB' 'HIV12AG') THEN PARCAT1N=4;
    ELSE PUT "WARN" "ING: Check LBCATs not mentioned: " LBCAT=;
/* 4) END KB 01May2014 */

    if parcatln = 1 then parcat1 = 'Clinical Chemistry';
    else if parcatln = 2 then parcat1='Hematology';
    else if parcatln = 3 then parcat1='Urinalysis';
    else if parcatln = 4 then parcat1='Safety Laboratory Entry
Criteria';

    * make urinalysis params unique from chem ;
    if lbcat = 'URINALYSIS' and lbtestcd in ('BILI' 'GLUC' 'PROT' 'RBC'
'WBC') then do;
        paramcd = 'U'||strip(lbtestcd);
        param = strip(lbtest)||' (Urine)';
    end;
    else do;
/* 5) START KB 01May2014 */

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/*          paramcd = lbtestcd;          */
/*          param = trim(lbtest);*/
/*          IF LBTESTCD NOT IN (/*'ALB' 'K'*/ 'BASO' /*'SODIUM' 'MCHC'*/ 'PLAT'
'WBC' 'EOS' 'LYM' 'MONO' 'NEUT' /*'RBC'*/) THEN DO;          /* 22) KB 14May2014
*/
          PARAMCD = LBTESTCD;
          PARAM = TRIM(LBTEST);
          END;
          ELSE DO;
              IF DFLAG NE 1 THEN DO; /* 55) KB 15Sep2014 */
                  PARAMCD=COMPRESS('O' || LBTESTCD);
                  PARAM=TRIM(LBTEST);
/* 55) START KB 15Sep2014 */
                  END;
                  ELSE DO;
                      PARAMCD=LBTESTCD;
                      PARAM=TRIM(LBTEST);
                      END;
/* 55) END KB 15Sep2014 */
                  END;
/* 5) END KB 01May2014 */
/*          /* 22) START KB 14May2014 */
/* 55) START KB 15Sep2014 */
/*          IF LBTESTCD IN ('ALB' 'K' 'SODIUM' 'MCHC' 'RBC') THEN DO;*/
/*          PARAMCD=COMPRESS('D' || LBTESTCD);*/
/*          PARAM=TRIM(LBTEST);*/
/*          END;*/
/* 55) END KB 15Sep2014 */
/* 22) END KB 14May2014 */
          end;
/* 5) START KB 01May2014 */
/*          IF PARAMCD NOT IN ('OK' 'OSODIUM' ) THEN DO;          /* /* 22) KB
14May2014 */
          if not missing(lbstresu) then param = strip(param) || ' (' ||
strip(lbstresu) || ')';
/* 22) START KB 14May2014 */
/*          END;*/
/*          ELSE DO;*/
/*          IF NOT MISSING(LBSTRESU) THEN PARAM = STRIP(PARAM) || ' (' ||
STRIP(LBORRESU) || ')';*/
/*          END;*/
/* 22) END KB 14May2014 */
/* 5) END KB 01May2014 */
          if lbtestcd = 'LBALL' then do;
              param = strip(param) || ' (' || strip(parcat1) || ')';
              paramcd = substr(parcat1,1,1) || strip(paramcd);
          end;
/* 10) START KB 01May2014 */
          IF PARAMCD='HBSAG' AND LBSTRESU EQ '' THEN PARAMCD='HBSAGC';
          ELSE IF PARAMCD='HCAB' AND LBSTRESU EQ '' THEN PARAMCD='HCABC';
/* 10) END KB 01May2014 */
          IF PARAMCD='HIV12AB' AND LBSTRESU EQ '' THEN PARAMCD='HIV12ABC'; /*
23) KB 14May2014 */

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* DO NOT CHANGE TESTCD OR PARAMN AFTER REXC-03 AS WE NEED TO BE
CONSISTENT BETWEEN STUDIES;
* clinical chemistry ;
if paramcd = /*'ALB'*//*'DALB'*/'ALB' then paramn = 14; /* 5) KB
01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'ALP' then paramn = 5;
else if paramcd = 'ALT' then paramn = 1;
else if paramcd = 'AST' then paramn = 2;
else if paramcd = 'BILDIR' then paramn = 4;
else if paramcd = 'BILI' then paramn = 3;
else if paramcd = 'BUN' then paramn = 11;
else if paramcd = 'CHOL' then paramn = 13;
else if paramcd = 'CREAT' then paramn = 9;
else if paramcd = 'GGT' then paramn = 6;
else if paramcd = 'GLUC' then paramn = 8;
else if paramcd = /*'K'*//*'DK'*/'K' then paramn = 16; /* 5) KB
01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'CLBALL' then paramn = 99;
else if paramcd = 'LDH' then paramn = 7;
else if paramcd = 'PROT' then paramn = 10;
else if paramcd = /*'SODIUM'*//*'DSODIUM'*/'SODIUM' then paramn =
15; /* 5) KB 01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'TRIG' then paramn = 12;
ELSE IF PARAMCD='OK' THEN PARAMN=76; /* 5) KB 01May2014 */
ELSE IF PARAMCD='OSODIUM' THEN PARAMN=75; /* 5) KB 01May2014 */
ELSE IF PARAMCD='OALB' THEN PARAMN=74; /* 5) KB 01May2014 */
* haematology;
else if paramcd = /*'BASO'*//*'DBASO'*/'BASO' then paramn = 113; /*
5) KB 01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'BASOLE' then paramn = 114;
else if paramcd = /*'EOS'*//*'DEOS'*/'EOS' then paramn = 111; /* 5)
KB 01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'EOSLE' then paramn = 112;
else if paramcd = 'HCT' then paramn = 103;
else if paramcd = 'HGB' then paramn = 102;
else if paramcd = 'HLBALL' then paramn = 199;
else if paramcd = /*'LYM'*//*'DLYM'*/'LYM' then paramn = 107; /* 5)
KB 01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'LYMLE' then paramn = 108;
else if paramcd = 'MCH' then paramn = 116;
else if paramcd = /*'MCHC'*//*'DMCHC'*/'MCHC' then paramn = 117; /*
5) KB 01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'MCV' then paramn = 118;
else if paramcd = /*'MONO'*//*'DMONO'*/'MONO' then paramn = 109; /*
5) KB 01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'MONOLE' then paramn = 110;
else if paramcd = /*'NEUT'*//*'DNEUT'*/'NEUT' then paramn = 105; /*
5) KB 01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = 'NEUTLE' then paramn = 106;
else if paramcd = /*'PLAT'*//*'DPLAT'*/'PLAT' then paramn = 115; /*
5) KB 01May2014 */ /* 55) KB 15Sep2014 */
else if paramcd = /*'RBC'*//*'DRBC'*/'RBC' then paramn = 101; /* 5)
KB 01May2014 */ /* 55) KB 15Sep2014 */

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        else if paramcd = /*'WBC'*//*'DWBC'*/'WBC' then paramn = 104; /* 5)
KB 01May2014 */ /* 55) KB 15Sep2014 */
/* 5) START KB 01May2014 */
    ELSE IF PARAMCD='OBASO' THEN PARAMN=173;
    ELSE IF PARAMCD='OEOS' THEN PARAMN=171;
    ELSE IF PARAMCD='OLYM' THEN PARAMN=167;
    ELSE IF PARAMCD='ONEUT' THEN PARAMN=165;
    ELSE IF PARAMCD='OPLAT' THEN PARAMN=175;
    ELSE IF PARAMCD='ORBC' THEN PARAMN=161;
    ELSE IF PARAMCD='OWBC' THEN PARAMN=164;
    ELSE IF PARAMCD='OMONO' THEN PARAMN=169;
    ELSE IF PARAMCD='OMCHC' THEN PARAMN=177;
/* 5) END KB 01May2014 */
    * serology;
    else if paramcd = 'HBSAG' then paramn = 301;
    else if paramcd = 'HCAB' then paramn = 302;
    else if paramcd = 'HIV12AB' then paramn = 303;
/* 10) START KB 01May2014 */
    ELSE IF PARAMCD = 'HBSAGC' THEN PARAMN = 304;
    ELSE IF PARAMCD = 'HCABC' THEN PARAMN = 305;
/* 10) END KB 01May2014 */
    ELSE IF PARAMCD='HIV12ABC' THEN PARAMN=306; /* 23) KB 14May2014 */
    * drug screen;
    else if paramcd = 'AMPHET' then paramn = 310;
    else if paramcd = 'BARB' then paramn = 311;
    else if paramcd = 'BNZDZPN' then paramn = 312;
    else if paramcd = 'CANNAB' then paramn = 313;
    else if paramcd = 'COCAINE' then paramn = 314;
    else if paramcd = 'OPIATE' then paramn = 315;
    *cotinine screen;
    else if paramcd = 'COTININE' then paramn = 320;
    *alcohol in urine;
    else if paramcd = 'ETHANOL' then paramn = 330;
    * pregnancy test;
    else if paramcd = 'PREGTEST' then paramn = 340;
    ELSE IF PARAMCD='SLBALL' THEN PARAMN=399; /* 24) KB 14May2014 */
    * urinalysis;
    else if paramcd = 'BACT' then paramn = 208;
    else if paramcd = 'UBILI' then paramn = 203;
    else if paramcd = 'CASTS' then paramn = 209;
    else if paramcd = 'CRYSTALS' then paramn = 210;
    else if paramcd = 'CYCAOXA' then paramn = 211;
    else if paramcd = 'DENISTY' then paramn = 212;
    else if paramcd = 'EPIROCE' then paramn = 213;
    else if paramcd = 'EPISQCE' then paramn = 214;
    else if paramcd = 'UGLUC' then paramn = 204;
    else if paramcd = 'ULBALL' then paramn = 299;
    else if paramcd = 'MUCUS' then paramn = 215;
    else if paramcd = 'NITRITE' then paramn = 205;
    else if paramcd = 'PH' then paramn = 201;
    ELSE IF PARAMCD = 'SPGRAV' THEN PARAMN = 202; /* 2) SM 30Nov2013 */
    else if paramcd = 'UPROT' then paramn = 207;
    else if paramcd = 'URBC' then paramn = 206;
    else if paramcd = 'UWBC' then paramn = 216;

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```

        else if paramcd = 'YEAST' then paramn = 217;
    ELSE IF PARAMCD='OCCBLD' THEN PARAMN=218; /* 19) KB 14May2014 */
        else put 'USER WARN' 'ING: parameter not allocated number: '
usubjid = lbcats = lbcat = lbcat = lbtestcd = ;

    * analysis variables ;

/* 5) START KB 01May2014 */
/*    aval = lbstresn;*/
/*    avalc = propcase(lbstresc, '.');*/
    IF PARAMCD NOT IN ('OBASO' 'OEOS' 'OLYM' 'ONEUT' 'OPLAT' /*'ORBC'*/
'OWBC' 'OMONO' /*'OALB' 'OK' 'OSODIUM' 'OMCHC'*/) THEN DO;    /* 22) KB
14May2014 */
        AVAL = LBSTRESN;
        AVALC = PROPCASE(LBSTRESC, '.');
    END;
    ELSE DO;
        IF LBORRES NE '-' THEN DO;
            AVAL=INPUT(LBORRES,BEST.);
            AVALC=PROPCASE(LBORRES, '.');
        END;
        ELSE DO;
            AVAL=.;
            AVALC=PROPCASE(LBORRES, '.');
        END;
    END;
/* 5) END KB 01May2014 */
    if avalc = 'Tntc' then avalc = tranwrd(avalc, 'Tntc', 'TNTC');
    avalu = strip(lbstresu);
    /*IF PARAMCD IN ('OK' 'OSODIUM') THEN AVALU=STRIP(LBORRESU);*/ /* 5)
KB 01May2014 */ /* 22) KB 14May2014 */
/*    if lb_flg ne 'Normal' then atoxgr = strip(lb_flg);*/ * only present
if not normal according to SAP; /* 18) KB 01May2014 */
/* 48) JM 28JUL2014 Start */
*ATOXGR=PROPCASE(LBTOXGR); /* 18) KB 01May2014 */
    IF TOXFLAG=1 THEN DO;
        IF MISSING(LBTOXGR) THEN ATOXGR='0';
        ELSE IF NOT MISSING(LBTOXGR) THEN
ATOXGR=PROPCASE(LBTOXGR);
    END;
/* 48) JM 28JUL2014 End*/
/* 11) START KB 01May2014 */
    IF NOT MISSING(LBNRIND) THEN DO;
        anrind = strip(lbnrind);
    END;
    ELSE DO;
        IF LB_FLG='!' THEN ANRIND='ABNORMAL';
    END;
/* 11) END KB 01May2014 */
/* 5) START KB 01May2014 */
/*    if missing(lbstnrc) then anrlo = strip(lbstnrc);*/
/*    else if not missing(lbstnrc) then anrlo = strip(lbstnrc);*/
/*    anrhi = strip(lbstnrhi);*/
    IF PARAMCD NOT IN ('OSODIUM' 'OK') THEN DO;

```

```

        IF MISSING(LBSTNRC) THEN DO;
            ANRLO = STRIP(LBSTNRLO);
            ANRHI = STRIP(LBSTNRHI);
        END;
/* 41) START KB 16May2014 */
        ELSE IF NOT MISSING(LBSTNRC) AND INDEX(LBSTNRC,'-') THEN DO;
            ANRLO = STRIP(SCAN(LBSTNRC,1,'-'));
            ANRHI = STRIP(SCAN(LBSTNRC,2,'-'));
        END;
/* 41) END KB 16May2014 */
        ELSE IF NOT MISSING(LBSTNRC) AND INDEXW(LBSTNRC,'TO')=0 THEN DO;
            ANRLO = STRIP(LBSTNRC);
            ANRHI = STRIP(LBSTNRHI);
        END;
        ELSE IF NOT MISSING(LBSTNRC) AND INDEXW(LBSTNRC,'TO') THEN DO;
            ANRLO = STRIP(SCAN(LBSTNRC,1,' '));
            ANRHI = STRIP(SCAN(LBSTNRC,3,' '));
        END;

    END;
    ELSE DO;
        IF MISSING(LBSTNRC) THEN DO;
            ANRLO = STRIP(LBSTNRLO);
            ANRHI = STRIP(LBSTNRHI);
        END;
/* 41) START KB 16May2014 */
        ELSE IF NOT MISSING(LBSTNRC) AND INDEX(LBSTNRC,'-') THEN DO;
            ANRLO = STRIP(SCAN(LBSTNRC,1,'-'));
            ANRHI = STRIP(SCAN(LBSTNRC,2,'-'));
        END;
/* 41) END KB 16May2014 */
        ELSE IF NOT MISSING(LBSTNRC) AND INDEXW(LBSTNRC,'TO')=0 THEN DO;
            ANRLO = STRIP(LBSTNRC);
            ANRHI = STRIP(LBSTNRHI);
        END;
        ELSE IF NOT MISSING(LBSTNRC) AND INDEXW(LBSTNRC,'TO') THEN DO;
            ANRLO = STRIP(SCAN(LBSTNRC,1,' '));
            ANRHI = STRIP(SCAN(LBSTNRC,3,' '));
        END;
        ANRHI = STRIP(LBORNHI);
    END;
/* 5) END KB 01May2014 */

    /* baseline flag;*/
/* 7) START KB 01May2014 */
/*  ablfl = lbbfl;*/
/*  IF VISIT='DAY 0' and index(lbtpt,'UNSCH')=0 THEN ABLFL='Y'; */ /*
49) KB 13Sep2014 */
/* 7) END KB 01May2014 */
/* IF VISIT='DAY -2' AND PARCAT1='Safety Laboratory Entry Criteria'
THEN ABLFL='Y';*/ /* 27) KB 15May2014 */ /* 49) KB 13Sep2014 */
/* IF (VISIT='SCREENING' */ /*OR INDEX(VISIT,'UNSCHE')*/ /*) AND PARAMCD
IN ('HBSAGC' 'HCABC' 'HIV12ABC') THEN ABLFL='Y';*/ /* 34) KB 15May2014 */
/* 44) KB 04Jun2014 */ /* 49) KB 13Sep2014 */

```

```

/* IF INDEX(PARAMCD,'LBALL') THEN ABLFL=''; *//* 37) KB 16May2014 */
/* 49) KB 13Sep2014 */

/*log flags;*/
if index(/*lbstresc*/AVALC,'<') then do; /* 31) KB 15May2014 */
    bloqfl = 'Y';
    /*aval = 0.5 * input(scan(lbstresc,2),best.);*/ * following
section 7.1 of SAP relating to biomarkers;
    AVAL=INPUT(TRANWRD(TRANWRD(AVALC,'<',''),'BLQ',''),BEST.)/2; /*
31) KB 15May2014 */
    aqlfl = 'Y';
end;
if paramcd ne 'COTININE' and index(lbstresc,'>') then do;
    aulqfl = 'Y';
    aval =
/*input(scan(lbstresc,2),best.)*/*INPUT(TRANWRD(AVALC,'>',''),BEST.); /*
42) KB 16May2014 */
    aqlfl = 'Y';
end;

/* 33) START KB 15May2014 */
IF INDEX(AVALC,'-') AND AVAL=. AND (MISSING(ANRLO) AND
MISSING(ANRHI)) THEN DO; /* 38) KB 16May2014 */
    ANRLO=SCAN(AVALC,1,'-');
    ANRHI=SCAN(AVALC,2,'-');
END;
/* 33) END KB 15May2014 */

* visit details ;
avisit = propcase(visit);
avisitn = visitnum;
atpt = propcase(lbtpt,'-');
atptn = lbtptnum;

/* 6) START KB 01May2014 */
/* if avisit = 'Unscheduled 1.01' then do;*/
/*     avisit = 'Screening - unscheduled';*/
/*     atpt = avisit;*/
/*     atptn = avisitn;*/
/* end;*/
/* 6) END KB 01May2014 */

* dates;
if length(lbdtc) gt 10 then do;
    adtm = input(lbdtc,e8601dt.);
    adt = datepart(adtm);
    atm = timepart(adtm);
end;
else if length(lbdtc) = 10 then adt = input(lbdtc,yymmdd10.);

/* 50) START KB 13Sep2014 */
IF NOT MISSING(LBCLSIG) AND MISSING(ACLSIG) THEN DO;

```

```

        ACLSIG=LBCLSIG;
    END;
/* 50) END KB 13Sep2014 */

    IF MISSING(AFASTFL) AND NOT MISSING(LBFAST) THEN AFASTFL=LBFAST; /*
57) KB 23Oct2014 */

    keep usubjid lbseq lbrefid param: parcat: aval: /*ablfl*/ avisit:
adt: atm lbstat lbreasnd lbdtc lbdy atoxgr anrind /* 49) KB 13Sep2014 */
    anrlo anrhi lbfast bloqfl aulqfl lbclsig lbspccnd atpt: DTYPE EPOCH
AQLFL TOXFLAG ACLSIG AFASTFL; /* 5) KB 01May2014 */ /* 16) KB 01May2014
*/ /* 50) KB 13Sep2014 */ /* 57) KB 23Oct2014 */
run;

/* 49) START KB 13Sep2014 */
/* 36) START KB 15May2014 */
/*DATA BASETEST;*/
/*    SET LB2(WHERE=(ABLFL='Y')) ;*/
/**/
/*    FLAG=1;*/
/*    KEEP USUBJID PARAMN FLAG;*/
/*RUN;*/
/**/
/*DATA ALLDATA;*/
/*    SET LB2;*/
/*    KEEP USUBJID PARAMN AVISITN;*/
/*RUN;*/
/**/
/*PROC SORT DATA=ALLDATA NODUPKEY;*/
/*    BY USUBJID PARAMN AVISITN;*/
/*RUN;*/
/**/
/*PROC SORT DATA=BASETEST NODUPKEY;*/
/*    BY USUBJID PARAMN;*/
/*RUN;*/
/**/
/*DATA BASETEST2;*/
/*    MERGE BASETEST ALLDATA;*/
/*    BY USUBJID PARAMN;*/
/*RUN;*/
/**/
/*PROC SORT DATA=BASETEST2(WHERE=(FLAG NE 1)) NODUPKEY;*/
/*    BY USUBJID PARAMN AVISITN;*/
/*RUN;*/
/**/
/*DATA BASETEST3;*/
/*    SET BASETEST2;*/
/**/
/*    ABLFL2='Y';*/
/*RUN;*/
/**/
/*PROC SORT DATA=LB2;*/
/*    BY USUBJID PARAMN AVISITN;*/
/*RUN;*/

```

```

/**/
/*DATA LB2A;*/
/*      MERGE LB2 BASETEST3;*/
/*      BY USUBJID PARAMN AVISITN;*/

/* IF ABLFL='' AND ABLFL2='Y' AND AVISITN IN (1 98 100) THEN
ABLFL='Y';*/ /* 39) KB 16May2014 */
/*      IF INDEX(PARAMCD,'LBALL') THEN ABLFL='';*/
/**/
/*      DROP FLAG ABLFL2;*/
/*RUN;*/
/* 36) END KB 15May2014 */

DATA SV;
    SET SDTM.SV(WHERE=(VISIT=('DAY 1')));
    FORMAT DAY DATE9.;

    DAY=INPUT(SCAN(SVSTDTC,1,'T'),YYMMDD10.);
    KEEP USUBJID DAY;
RUN;

DATA ABLFL;
    SET LB2(WHERE=(AVISIT IN ('Screening' 'Day -2' 'Day -1' 'Day 0' 'Day
1') AND LBSTAT NE 'NOT DONE'));

    KEEP USUBJID PARAMCD AVISIT ADTM ATPT ADT;
RUN;

PROC SORT DATA=ABLFL;
    BY USUBJID;
RUN;

DATA ABLFL2;
    MERGE ABLFL(IN=A) SV;
    BY USUBJID;
    IF A;
RUN;

DATA ADSLTM;
    SET ADAM.ADSL;
    WHERE TRT01A IN ('CC' 'THS 2.2' 'SA');

    KEEP USUBJID TRTSDTM TRT01A;
RUN;

DATA ABLFL2A;
    MERGE ABLFL2(IN=A) ADSLTM;
    BY USUBJID;
    IF A;
RUN;

PROC SORT DATA=ABLFL2A;
    BY USUBJID PARAMCD ADTM;
RUN;

```

```

DATA ABLFL3;
  SET ABLFL2A;

  IF TRT01A='SA' THEN DO;
    IF DAY NE . THEN DO;
      IF ADTM<DHMS(DAY,6,30,0) AND
INDEX(UPCASE(AVISIT),'UNSCHED')=0 AND INDEX(UPCASE(ATPT),'UNSCHED')=0
THEN ABLFL2='Y';
      END;
    ELSE IF DAY EQ . THEN DO;
      IF INDEX(UPCASE(AVISIT),'UNSCHED')=0 AND
INDEX(UPCASE(ATPT),'UNSCHED')=0 THEN ABLFL2='Y';
      END;
    END;
  ELSE IF TRT01A IN ('CC' 'THS 2.2') THEN DO;
    IF ADTM<TRTSDTM AND INDEX(UPCASE(AVISIT),'UNSCHED')=0 AND
INDEX(UPCASE(ATPT),'UNSCHED')=0 THEN ABLFL2='Y';
    END;
  ELSE IF MISSING(TRT01A) THEN DO;
    IF INDEX(UPCASE(AVISIT),'UNSCHED')=0 AND
INDEX(UPCASE(ATPT),'UNSCHED')=0 THEN ABLFL2='Y';
    END;
RUN;

PROC SORT DATA=ABLFL3(WHERE=(ABLFL2='Y')) OUT=ABLFL4;
  BY USUBJID PARAMCD ADT ADTM;
RUN;

DATA ABLFL5(WHERE=(ABLFL='Y'));
  SET ABLFL4;
  BY USUBJID PARAMCD ADT ADTM;
  FORMAT ABLFL $2.;

  IF LAST.PARAMCD THEN ABLFL='Y';

  KEEP USUBJID PARAMCD AVISIT ABLFL;
RUN;

PROC SORT DATA=ABLFL5;
  BY USUBJID PARAMCD AVISIT;
RUN;

PROC SORT DATA=LB2;
  BY USUBJID PARAMCD AVISIT;
RUN;

DATA LB2A;
  MERGE LB2 ABLFL5;
  BY USUBJID PARAMCD AVISIT;
RUN;
/* 49) END KB 13Sep2014 */

*****;

```



```

* change from baseline ;
*****;
proc sort data = /*lb2*/LB2A; /* 36) KB 16May2014 */
    by usubjid paramn PARCAT1 avalu; /* 8) KB 01May2014 */
run;

data base(keep = usubjid paramn avalu base: bvis btoxgr bnrind PARCAT1
BLBCLSIG); /* 8) KB 01May2014 */ /* 52) KB 13Sep2014 */
    set /*lb2*/LB2A(where = (ablfl = 'Y')); /* 36) KB 16May2014 */
    format base best. basec $20. bnrind $50. btoxgr $20.;
    base = aval;
    basec = avalc;
    bvis = avisitn;
    btoxgr = strip(atoxgr);
    bnrind = anrind;
    BLBCLSIG=ACLSIG; /* 52) KB 13Sep2014 */
run;

proc sort data=base dupout=base2 nodupkey;
    by usubjid paramn parcat1 avalu;
run;

data change(drop = bvis BLBCLSIG); /* 52) KB 13Sep2014 */
    merge /*lb2*/LB2A base; /* 36) KB 16May2014 */
    by usubjid paramn PARCAT1 avalu; /* 8) KB 01May2014 */
    format chg best. shift1 shift2 $50.;
    if avisitn gt bvis then do;
        CHG=ROUND(AVAL-BASE,0.0000000001); /* 25) KB 15May2014 */
/*        chg = aval - base;*/
/* 52) START KB 13Sep2014 */
/*        if not missing(bnrind) then shift1 = propcase(strip(bnrind))
|| ' to ' ||propcase(strip(anrind));*/
        IF NOT MISSING(BNRIND) THEN DO;
            IF NOT MISSING(BLBCLSIG) AND NOT MISSING(ACLSIG) THEN SHIFT1
= PROPCASE(STRIIP(BNRIND)) || ', ' || STRIP(BLBCLSIG) || ' to '
||PROPCASE(STRIIP(ANRIND)) ||', ' || STRIP(ACLSIG);
            ELSE IF NOT MISSING(BLBCLSIG) AND MISSING(ACLSIG) THEN
SHIFT1=PROPCASE(STRIIP(BNRIND)) || ', ' || STRIP(BLBCLSIG) || ' to '
||PROPCASE(STRIIP(ANRIND));
            ELSE IF MISSING(BLBCLSIG) AND NOT MISSING(ACLSIG) THEN
SHIFT1=PROPCASE(STRIIP(BNRIND)) || ' to ' ||PROPCASE(STRIIP(ANRIND)) || ',
' || STRIP(ACLSIG);
            ELSE IF MISSING(BLBCLSIG) AND MISSING(ACLSIG) THEN
SHIFT1=PROPCASE(STRIIP(BNRIND)) || ' to ' ||PROPCASE(STRIIP(ANRIND));
        END;
/* 52) END KB 13Sep2014 */

        IF NOT MISSING(BNRIND) AND MISSING(ANRIND) THEN SHIFT1=''; /*
11) KB 01May2014 */
/* 48) JM 28JUL2014 start*/
/*
    if missing(btoxgr) and not missing(basec) then do;
        if missing(atoxgr) then shift2 = 'Normal to Normal';

```

```

        else if not missing(atoxgr) then shift2 = 'Normal to '
|| ' ' || strip(atoxgr);
        end;
        else if not missing(btoxgr) then do;
            if missing(atoxgr) then shift2 = strip(btoxgr) || ' to
Normal';
            else if not missing(atoxgr) then shift2 = strip(btoxgr)
|| ' to ' || strip(atoxgr);
            end;
        */
        IF TOXFLAG=1 THEN DO;
            if missing(btoxgr) and not missing(basec) then do;
                if missing(atoxgr) then shift2 = 'Normal to
Normal';
                else if not missing(atoxgr) then shift2 = 'Normal
to ' || ' ' || strip(atoxgr);
                end;
            else if not missing(btoxgr) then do;
                if missing(atoxgr) then shift2 = strip(btoxgr) ||
' to Normal';
                else if not missing(atoxgr) then shift2 =
strip(btoxgr) || ' to ' || strip(atoxgr);
                end;
            END;
        /* 48) JM 28JUL2014 end*/
        end;
run;

proc sort data = change;
    by usubjid paramn avisitn atptn;
run;

data change2;
    set change;
    by usubjid paramn avisitn atptn;
    format anl01fl $2.;

    * determine if any unscheduled;
    if index(upcase(avisit),'UNSCHEDULED') OR
INDEX(UPCASE(ATPT),'UNSCHED') OR MISSING(ATPT) or index(paramcd,'LBALL')
then anl01fl = ' '; /* 12) KB 01May2014 */ /* 54) KB 15Sep2014 */
    else if last.atptn and first.atptn = 0 then anl01fl = ' ';
    else anl01fl = 'Y';
    if anl01fl = ' ' then put 'Check reason for exclusion from
analysis: ' usubjid = param = avisit = atpt =;
    if paramcd in ('URBC' 'HIV12ABC' 'HBSAG' 'HCAB' 'HIV12AB' 'HBSAGC'
'HCABC' 'AMPHET' 'BACT' 'BARB' 'BNZDZPN' 'CANNAB' 'CASTS' 'COCAINE'
'CRYSTALS' /* 12) KB 01May2014 */ /* 32) KB 15May2014 */ /* 35) KB
15May2014 */
    'CYCAOXA' 'DENISTY' 'EPIROCE' 'EPISQCE' 'ETHANOL' 'MUCUS'
'OPIATE' 'PREGTEST' /*'WBC'*/ 'UWBC' 'YEAST' 'COTININE') then anl01fl =
' '; /* 1) SM 30Nov2013 */ /* 12) KB 01May2014 */

```

```
        IF PARAMCD IN ('OALB' 'OBASO' 'OEOS' 'OLYM' 'ONEUT' 'OPLAT' 'ORBC'
'OWBC' 'OMONO' 'OK' 'OSODIUM' 'OMCHC') THEN ANL01FL=' '; /* 5) KB
01May2014 */
run;
```

```
* end of exposure flag;
proc sort data = change2 out = eos(where = (not missing(avalc)));
    by usubjid paramn avisitn atptn adtm;
run;
```

```
/* 40) START KB 16May2014 */
DATA ADSLVIS;
    SET ADAM.ADSL;
    KEEP USUBJID LVISDT;
RUN;
```

```
DATA EOSVIS;
    MERGE EOS(IN=A) ADSLVIS;
    BY USUBJID;
    IF A;

    IF ADT<=LVISDT THEN LVISFLG='Y';
RUN;
```

```
PROC SORT DATA=EOSVIS;
    BY USUBJID PARAMN AVISITN;
RUN;
/* 40) END KB 16May2014 */
```

```
data eos2(keep = usubjid paramn avisitn /*atptn*/ aeosfl); /* 13) KB
01May2014 */
    set /*eos*/EOSVIS(WHERE=(LVISFLG='Y')); /* 40) KB 16May2014 */
    format aeosfl $2.;
    by usubjid paramn AVISITN; /* 13) KB 01May2014 */
    if last.paramn AND LAST.AVISITN then do; /* 13) KB 01May2014 */
        aeosfl = 'Y';
        output;
    end;
run;
```

```
*merge back onto data;
data lb3;
    merge change2 eos2;
    by usubjid paramn avisitn /*atptn*/; /* 13) KB 01May2014 */
run;
```

```
/* 13) START KB 01May2014 */
DATA EOS3(KEEP = USUBJID PARAMN EOS);
    SET /*EOS*/EOSVIS(WHERE=(LVISFLG='Y')); /* 40) KB 16May2014 */
    FORMAT EOS BEST.;
    BY USUBJID PARAMN;
    IF LAST.PARAMN THEN DO;
        EOS=AVAL;
        OUTPUT;
    END;
```

```

        END;
RUN;

DATA LB4;
    MERGE LB3 EOS3;
    BY USUBJID PARAMN;
RUN;
/* 13) END KB 01May2014 */

*****;
* Combine ADSL and QS data *;
*****;
* treatment period;
*_mtotper;

data sllb(drop = trt01: tr01:);
    merge adsl /*lb3*/LB4(in = a); /* 13) KB 01May2014 */
    by usubjid;
    if a;          * only include subjects with data ;
    format aperiod trtan trtpn aday 8. trta trtp $40. aperiodc $10.;
    aday = adt - trtsdt + 1;
    * allocate tretament and period;
    *_mperall(dvar1 = adtm, dvar2 = adt);
    aperiodc = 'Period ' || put(aperiod,1.);

    IF PARAMTYP='DERIVED' THEN LBDTC=''; /* 15) KB 01May2014 */
    drop TOXFLAG;
run;

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

options replace;

data adlb;
    set stdlib.adlb sllb;
run;

proc sort data = adlb out = adam.adlb(label = 'Laboratory Analysis
Dataset');
/*    by usubjid avisitn atptn parcatln paramn;*/
    BY USUBJID AVISITN ATPTN PARAMCD; /* 14) KB 01May2014 */ /* 43) KB
04Jun2014 */
run;

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

```