

```

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_2ADEL.sas;
%put NOTE: Purpose : create ADEL dataset;
%put NOTE: ;
%put NOTE: Input Data : STDLIB.ADEL SDTM.IE ADAM.ADSL;
%put NOTE: Output : ADAM.ADEL;
%put NOTE: Macros Called : _MPRINTTO;
%put NOTE: ;
%put NOTE: Programmed by : cvn_smulholl;
%put NOTE: Creation Date : 2013-09-23;
%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: 02Dec2013 SM 1) Remove VISITx variables and update
for new version;
%put NOTE: 03Dec2013 SM 2) Extend PARAM to 400;
%put NOTE: 01May2014 KB 3) Amended code to use CRF data;
%put NOTE: 01May2014 KB 4) Amended import to use specs macro
variable;
%put NOTE: 01May2014 KB 5) Amended PARAM for special
characters;
%put NOTE: 01May2014 KB 6) Added PARAMCD;
%put NOTE: 01May2014 KB 7) Amended final section of code to
match previous studies;
%put NOTE: 14May2014 KB 8) Added format to APERIODC;
%put NOTE: 27Jul2014 KB 9) Added EXNOTRFL;
%put NOTE: 14Sep2014 KB 10) Added COMPLFL FUPFL FASFL & PPROTFL
to ADSL keep;
%put NOTE:
=====;
options notes source source2 nofullstimer validvarname=upcase missing='
';
ods _all_ close;
ods listing;

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

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*****;
* bring in ADSL ;
*****;

data adsl;
    set adam.adsl;
    keep studyid usubjid subjid: siteid age sex: race height weightb1
bmi ucpdgr: nicogr: targr: cobl
        scrffl saffl randfl tr01: trt01: dthfl enfl EXNOTRFL exfl
trtsdt COMPLFL FUPFL FASFL PPROTFL; /* 9) KB 27Jul2014 */ /* 10) KB
14Sep2014 */
run;

proc sort data = adsl;
    by usubjid;
run;
*****;
* import inclusion / exclusion text ;
*****;

PROC IMPORT
/*      DATAFILE="/cvn/projects/prj/data/000000106324/source/ZRHR_REXC-
03_ADaM_Specifications_v0.5.xlsx"*/
    DATAFILE="/cvn/projects/prj/data/000000106324/source/ZRHR_REXC-
03_ADaM_Specifications_v&specs..xlsx" /* 4) KB 01May2014 */
    OUT=WORK.ietexta
    REPLACE
    DBMS=XLSX;
    RANGE="ValueLevelMetadata$A2:D419";
    GETNAMES=NO;
RUN;

data ietext(drop = a b c d);
    set ietexta(where=(index(a,'ADEL')));
    format param $200./*$400.*//*200*/ PARAMCD $8.; /* 2) SM 03Dec2013
*/ /* 6) KB 01May2014 */
/*    param = left(trim((d)));*/
    PARAM=COMPRESS(D,'>','kw'); /* 5) KB 01May2014 */
    * unable to combine on single variable due to format of data input
from xlsx file;
/* 6) START KB 01May2014 */
/*    ie = substr(c,1,3);*/
/*    num = input(substr(c,4,2),best.);*/
    IF INDEX(C,'INC') OR INDEX(C,'EXC') THEN DO;
        IE = SUBSTR(C,1,3);
        NUM = INPUT(SUBSTR(C,4,2),BEST.);
    END;
    ELSE DO;
        IE=C;
    END;

    IF NUM<10 THEN DO;
        PARAMCD=COMPRESS(IE||'0'||NUM);

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        END;
        ELSE DO;
            PARAMCD=COMPRESS(IE||NUM);
        END;
    /* 6) END KB 01May2014 */
run;

*****;
* bring in IE      ;
*****;
/* 3) START KB 01May2014 */
/*data ie;*/
/*    set sdtm.ie;*/
/*    format parcat1 $40. parcatln avisitn 8. paramcd $8. avisit $40.  */
/*          adt date9. avalc $2.;*/
/*    paramcd = ietestcd;*/
/*    ie = substr(ietestcd,1,3);*/
/*    num = input(substr(ietestcd,4,2),best.);*/
/*    parcat1 = trim(iecat);*/
/*    if parcat1 = 'INCLUSION' then parcatln = 1;*/
/*    else if parcat1 = 'EXCLUSION' then parcatln = 2;*/
/*    avalc = iestresc;*/
/*    avisitn = visitnum;*/
/*    avisit = propcase(visit);*/
/*    if not missing(iedtc) then adt = input(iedtc,ymmdd10.);*/
/*    adtm = .;*/  * set value for period macro below;
/*    keep usubjid ieseq param: parcat1: avalc visitdy visitnum visit
avisit: */
/*          adt adtm  iedtc iedy ie num;*/
/*run;*/

/* 3) START KB 01May2014 */
/* CRF data - obtaining all inclusion data */
DATA INCS_SC;
    SET CRF.IE_I;
    FORMAT AVALC $2. PARAMCD $8. AVISIT $40.;

    IF IE_I_ORRES='Yes' THEN AVALC='Y';
    ELSE IF IE_I_ORRES='No' THEN AVALC='N';
    ELSE IF IE_I_ORRES='NA' THEN AVALC='NA';
    ELSE IF IE_I_ORRES='Not Done' THEN AVALC='ND';
    ELSE PUT "WARN" "ING: Check IE data for AVALC " IE_I_ORRES=;

    IETEST1=INPUT(IETEST_I_STD,BEST.);

    AVISIT=PROPCASE(FOLDERNAME);

    IF IETEST1<10 THEN DO;
        PARAMCD=COMPRESS('INC0'||IETEST1);
    END;
    ELSE DO;
        PARAMCD=COMPRESS('INC'||IETEST1);
    END;

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        KEEP SUBJECT PARAMCD AVALC AVISIT IETEST1;
RUN;

DATA INCS_ADM;
    SET CRF.IE_I_ADM;
    FORMAT AVALC $2. PARAMCD $8. AVISIT $40.;

    AVISIT=PROPCASE(FOLDERNAME);

    IF IE_I_ORRES='Yes' THEN AVALC='Y';
    ELSE IF IE_I_ORRES='No' THEN AVALC='N';
    ELSE IF IE_I_ORRES='NA' THEN AVALC='NA';
    ELSE IF IE_I_ORRES='Not Done' THEN AVALC='ND';
    ELSE PUT "WARN" "ING: Check IE data for AVALC " IE_I_ORRES=;

    IETEST1=INPUT(IETEST_I_STD,BEST.);

    IF IETEST1<10 THEN DO;
        PARAMCD=COMPRESS('INC0' || IETEST1);
    END;
    ELSE DO;
        PARAMCD=COMPRESS('INC' || IETEST1);
    END;

    KEEP SUBJECT PARAMCD AVALC AVISIT IETEST1;
RUN;

DATA INCS_SF;
    SET CRF.IE_I_SF;
    FORMAT AVALC $2. PARAMCD $8. AVISIT $40.;

    IF IE_I_ORRES1='Yes' THEN AVALC='Y';
    ELSE IF IE_I_ORRES1='No' THEN AVALC='N';
    ELSE IF IE_I_ORRES1='NA' THEN AVALC='NA';
    ELSE IF IE_I_ORRES1='Not Done' THEN AVALC='ND';
    ELSE PUT "WARN" "ING: Check IE data for AVALC " IE_I_ORRES1=;

    IETEST1=INPUT(IETEST_I_STD,BEST.);

    AVISIT='Screening';

    IF IETEST1<10 THEN DO;
        PARAMCD=COMPRESS('INC0' || IETEST1);
    END;
    ELSE DO;
        PARAMCD=COMPRESS('INC' || IETEST1);
    END;

    KEEP SUBJECT PARAMCD AVALC AVISIT IETEST1;
RUN;

DATA INCS;
    SET INCS_SC INCS_ADM INCS_SF;

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RUN;

PROC SORT DATA=INCS;
  BY SUBJECT;
RUN;

/* CRF data - obtaining all exclusion data */
data excs_sc;
  set crf.ie_e;
  FORMAT AVALC $2. PARAMCD $8. AVISIT $40.;

  avisit=propcase(foldername);

  if ie_e_orres='Yes' THEN AVALC='Y';
  ELSE IF IE_E_ORRES='No' THEN AVALC='N';
  ELSE IF IE_E_ORRES='NA' THEN AVALC='NA';
  ELSE IF IE_E_ORRES='Not Done' THEN AVALC='ND';
  ELSE PUT "WARN" "ING: Check IE data for AVALC " IE_E_ORRES=;

  IETEST1=INPUT(IETEST_STD,BEST.);

  IF IETEST1<10 THEN DO;
    PARAMCD=COMPRESS('EXC0' || IETEST1);
  END;
  ELSE DO;
    PARAMCD=COMPRESS('EXC' || IETEST1);
  END;

  KEEP SUBJECT PARAMCD AVALC AVISIT IETEST1;
RUN;

DATA EXCS_ADM;
  SET CRF.IE_E_ADM;
  FORMAT AVALC $2. PARAMCD $8. AVISIT $40.;

  IF IE_E_ORRES='Yes' THEN AVALC='Y';
  ELSE IF IE_E_ORRES='No' THEN AVALC='N';
  ELSE IF IE_E_ORRES='NA' THEN AVALC='NA';
  ELSE IF IE_E_ORRES='Not Done' THEN AVALC='ND';
  ELSE PUT "WARN" "ING: Check IE data for AVALC " IE_E_ORRES=;

  IETEST1=INPUT(IETEST_STD,BEST.);

  AVISIT=PROPCASE(FOLDERNAME);

  IF IETEST1<10 THEN DO;
    PARAMCD=COMPRESS('EXC0' || IETEST1);
  END;
  ELSE DO;
    PARAMCD=COMPRESS('EXC' || IETEST1);
  END;

  KEEP SUBJECT PARAMCD AVALC AVISIT IETEST1;
RUN;

```

```

DATA EXCS_SF;
  SET CRF.IE_E_SF;
  FORMAT AVALC $2. PARAMCD $8. AVISIT $40.;

  IF IE_E_ORRES1='Yes' THEN AVALC='Y';
  ELSE IF IE_E_ORRES1='No' THEN AVALC='N';
  ELSE IF IE_E_ORRES1='NA' THEN AVALC='NA';
  ELSE IF IE_E_ORRES1='Not Done' THEN AVALC='ND';
  ELSE PUT "WARN" "ING: Check IE data for AVALC " IE_E_ORRES1=;
  IETEST1=INPUT(IETEST_STD,BEST.);

  AVISIT='Screening';

  IF IETEST1<10 THEN DO;
    PARAMCD=COMPRESS('EXC0' || IETEST1);
  END;
  ELSE DO;
    PARAMCD=COMPRESS('EXC' || IETEST1);
  END;

  KEEP SUBJECT PARAMCD AVALC AVISIT IETEST1;
RUN;

DATA EXCS;
  SET EXCS_SC EXCS_ADM EXCS_SF;
RUN;

PROC SORT DATA=EXCS;
  BY SUBJECT;
RUN;

DATA ALL;
  SET INCS EXCS;
  BY SUBJECT;
  LENGTH USUBJID $24.;
  USUBJID=COMPRESS('ZHRH-REXC-03-EU-BIO-' || SUBJECT);

RUN;

PROC SORT DATA=ALL;
  BY SUBJECT AVISIT;
RUN;

DATA DATES;
  SET SDTM.SV (WHERE=(VISIT IN ('SCREENING' 'DAY -2')) KEEP=VISIT
USUBJID VISIT SVSTDTC);
  ATTRIB ADT FORMAT=DATE9.
  SUBJECT LENGTH=$150.
  AVISIT FORMAT=$40.;
  SUBJECT=SCAN(USUBJID,6,'-');
  ADT=INPUT(SVSTDTC,YYMMDD10.);
  AVISIT=PROPCASE(VISIT);
  IF AVISIT='Day -2' THEN AVISIT='Admission (Day -2)';

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RUN;

PROC SORT DATA=DATES;
  BY SUBJECT AVISIT;
RUN;

DATA ALL2;
  MERGE ALL(IN=A) DATES;
  BY SUBJECT AVISIT ;
  FORMAT PARAMN 8.;

  IF A;
  IF INDEX(PARAMCD,'INC') THEN PARAMN=INPUT(SCAN(PARAMCD,2,'C'),BEST.);
  ELSE IF INDEX(PARAMCD,'EXC') THEN
PARAMN=INPUT(SCAN(PARAMCD,2,'C'),BEST.)+8;

  DROP VISIT;
run;

PROC SORT DATA=ALL2;
  BY SUBJECT DESCENDING AVISIT PARAMCD;
RUN;

DATA ALL3;
  SET ALL2;
  ATTRIB AVISITN FORMAT=8.;
  IF AVISIT='Screening' THEN DO;
    AVISITN=1;
    EPOCH='SCREENING';
  END;
  ELSE IF AVISIT='Admission (Day -2)' THEN DO;
    AVISITN=98;
    EPOCH='ADMI';
    AVISIT='Day -2';
  END;
RUN;

PROC SORT DATA=ALL3;
  BY SUBJECT AVISITN PARAMN IETEST1;
RUN;
/* 3) END KB 01May2014 */

*****;
* merge in full inclusion/exclusion text ;
*****;

proc sql;
  create table ie2 as
  select a.*, b.param
  from /*ie*/ALL3 as a left join ietext as b /* 3) KB 01May2014 */
  on a.PARAMCD/*ie*/ = b.PARAMCD/*ie and a.num=b.num*/ /* 6) KB
01May2014 */
  where a.PARAMCD/*ie*/ = b.PARAMCD/*ie and a.num=b.num*/ /* 6) KB
01May2014 */

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        order by usubjid;
quit;
```

```
*****;
* Combine ADSL and IE data *;
*****;
* find periods ;
*_mtotper;

/* 7) START KB 01May2014 */
/*data slie(drop = ie num trt01: tr01: adtm trtsdt VISIT:); *//* 1)
02Dec2013 */
/* merge adsl ie2(in = a);*/
/* by usubjid;*/
/*if a; */ * only include subject level data is eligibilty
issues ;
/* format aperiod trtan trtpn aday 8. trta trtp $40. aperiodc $10.;*/
/* if not missing(adtm) and not missing(trtsdt) then aday = adtm -
trtsdt + 1;*/
/* allocat treatment / period ;
/* _mperall(dvar1 = adtm, dvar2 = adtm);*/
/* aperiodc = 'Period ' || put(aperiod, 1.);*/
/*run;*/

DATA SLIE(DROP=TRT01: TR01: TRTSDT SUBJECT EPOCH IETEST1 SVSTDTC ADTM);
MERGE ADSL IE2(IN = A);
BY USUBJID;
IF A; * only include subject level data is eligibilty issues ;
FORMAT ADAY 8. PARCAT1 $40. PARCAT1N 8. APERIODC $10.; /* 8) KB
14May2014 */
IF NOT MISSING(ADTM) AND NOT MISSING(TRTSDT) THEN ADAY = ADTM -
TRTSDT + 1;

ADTM=.;
*_MPERALL(DVAR1 = ADTM, DVAR2 = ADTM);
APERIODC = 'Period ' || PUT(APERIOD, 1.);

IF (PARAMCD='EXC18' OR PARAMCD='EXC19') AND SEXC='Male' THEN
AVALC='NA';

IF INDEX(PARAMCD,'INC') THEN DO;
PARCAT1='INCLUSION';
PARCAT1N=1;
END;
ELSE DO;
PARCAT1='EXCLUSION';
PARCAT1N=2;
END;
RUN;

/* 7) END KB 01May2014 */
```



```

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

options replace;

data adie;
    set stdlib.adel slie;
    label aperiodc = 'Period (C)';
run;

proc sort data = adie out = adam.adel(label = 'Eligibility Analysis
Dataset');
    by usubjid avisitn paramcd;
run;

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

```