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/*=====
| Covance Study Number   : 000000106343
| Program Name           : adcm.sas
| Purpose                : Create Adam Dataset (ADEL)
| Input Data             : adsl ,sdm.ie
| Output Data            : adma.adel
|
| Macros Called          :
| Originally Performed by :paddepalli
| Date                   : 13Mar2015
|=====
| Modification History : Original Version
|-----
| Modified by          :
| Modification Date    :
| Modification Reason   :
| Program Version      :
|=====*/

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%m_printto(route=YES);
options validvarname=upcase missing=' ';
libname sdm "/cvn/projects/prj/data/000000106343/datasets/sdm/sdtm";

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

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*****;
* bring in IE from sdm.ie ;
*****;
/*data ie;*/
/*set sdm.ie;*/
/* keep usubjid iecat ietest ietestcd iestresc visit visitnum iedtc;*/
/* run;*/

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* Note-to-file CDARO #9: Covance programmers will be required to hard code the exclusion of subject 1108 and 1109 when reporting data from the Criteria files IE_I and IE_E. ;

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data ie_e;
  set crf.ie_e;
  if subject in ('1108', '1109') then delete;
run;

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data ie_i;
  set crf.ie_i;
  if subject in ('1108', '1109') then delete;
run;
data ie_all;*(rename=(sitenum=siteid));
  set ie_i crf.ie_i_adm crf.ie_i_sf ie_e crf.ie_e_adm crf.ie_e_sf;
/*if IE_I_ORRES ='No' or IE_I_ORRES1='No' or IE_E_ORRES ='Yes' or IE_E_ORRES1='Yes' ; */
  drop sitenum;
  rename siteid=sitenum;
/*keep subject siteid;*/
run;

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data ie;
  length paramcd $8 param $200 parcat1 $60 parcat1N 8 avalc $2 avisit $40 avisitN 8;
set ie_all;
If index(upcase(datapagename), 'EXCLUSION ') then PARCAT1='EXCLUSION' ;
else if index(upcase(datapagename),'INCLUSION') then PARCAT1 = 'INCLUSION';
if input(ietestcd,5.) < 10 then do;
If parcat1 = 'EXCLUSION' then
paramcd = 'EXC' || '0' || IETESTCD;
else if parcat1 = 'INCLUSION' then
paramcd = 'INC' || '0' || IETESTCD;
end;
if input(ietestcd,5.) >= 10 then do;
if parcat1 = 'EXCLUSION' then
paramcd = 'EXC' || IETESTCD;
else if parcat1 = 'INCLUSION' then
paramcd = 'INC' || IETESTCD;
end;

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if index(upcase(datapagename), 'EXCLUSION ') and IE_E_ORRES_STD ne "" then avalc= IE_E_ORRES_STD;

else if index(upcase(datapagename), 'EXCLUSION ') and IE_E_ORRES_STD = "" then avalc= IE_E_ORRES1_STD;
else if index(upcase(datapagename),'INCLUSION') and IE_I_ORRES_STD ne "" then avalc= IE_I_ORRES_STD;

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else if index(upcase(datapagename),'INCLUSION') and IE_I_ORRES_STD = "" then avalc= IE_I_ORRES1_STD;

if foldername in ('Screening','Screen Failure') then do;avisit='Screening';avisitn=1;end;
else if foldername='Admission (Day -2)' then do; avisit='Day -2';avisitn=98;end;
/*data iel;*/
/* length paramcd $8 param $200 parcat1 $60 parcat1n 8 avalc $2 avisit $40 avisitn adt 8;*/
/*set ie;*/
/*paramcd=ietestcd;*/
/*parcat1=iecat;*/
/* avalc=iestresc;*/
/* avisit=visit;*/
/* avisitn=visitnum;*/
/* ADT= input(iedtc,yymmdd10.);*/
/* format adt date9.;*/

if parcat1 = "INCLUSION" then parcat1n=1;
else parcat1n=2;

    if PARAMCD = "INC01" then do;
        PARAM = "Subject has signed the ICF and is able to understand the information provided in the Subject Information Sheet and ICF
.";
        PARAMN = 1;
    end;
    else if PARAMCD = "INC02" then do;
PARAM = "Subject is at a minimum 22 years of age (inclusive).";
PARAMN = 2; end;
    else if PARAMCD = "INC03" then do;
PARAM = "Smoking, but healthy subject based on all available assessments from screening/day of admission."; PARAMN = 3; end;

    else if PARAMCD = "INC04" then do;
        PARAM = "Current smoker, who has smoked at least 10 commercially available mCCs per day for 4 weeks and has smoked for the past
3 years. Status verified with cotinine test.";
        PARAMN = 4;
    end;
    else if PARAMCD = "INC05" then do;
        PARAM = "The subject is a current smoker who does not plan to quit smoking within the next 6 months";
        PARAMN = 5;
    end;
    else if paramcd = "INC06" then do; param = "The subject is ready to comply with study protocol."; paramn = 6; end;

    else if PARAMCD = "EXC01" then do;
        PARAM = "As per investigator or designee judgment, the subject cannot participate in the study for any reason (e.g., medical, p
sychiatric, and/or social reason).";
        PARAMN = 7;
    end;
    else if paramcd = "EXC02" then do;
param = "Subject is legally incompetent, physically or mentally incapable of giving consent."; paramn = 8; end;

    else if paramcd = "EXC03" then do;
        PARAM = "Subject has clinically relevant diseases which required medications, which in the opinion of the investigator would je
opardize the safety of the subject.";
        PARAMN = 9;
    end;
    else if paramcd = "EXC04" then do;
        PARAM = "Subject who has forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC)<0.7 and FEV1<80% predicted value
at post bronchodilator spirometry.";
        PARAMN = 10;
    end;
    else if paramcd = "EXC05" then do;
        PARAM = "Subject with asthma condition (FEV1/FVC) <0.75 and reversibility in FEV1>12% from pre to post-bronchodilator values.";
        PARAMN = 11;
    end;
    else if paramcd = "EXC06" then do;
        PARAM = "Subject with renal insufficiency as defined by serum creatinine levels of >1.3mg/dL for female and >1.5 mg/dL for male
s.";
        PARAMN = 12;
    end;
    else if paramcd = "EXC07" then do;
param = "The subject has a body mass index (BMI) <18.5 or =>32 kg/m2."; paramn = 13; end;

    else if paramcd = "EXC08" then do;
        PARAM = "Subject has medical conditions which require/will require during the study, a medical intervention which may interfere
with study participation/results.";
        PARAMN = 14;
    end;
    else if paramcd = "EXC09" then do;
param = "Any subject with an history of adverse events linked to caffeine or caffeine containing drugs, such as but not limited to h
ypersensitivity or allergy.";

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paramn = 15; end;

    else if paramcd = "EXC10" then do;
        PARAM = "Subject has used nicotine containing products other than commercially available CC, within 4 weeks prior to assessment
        .";
        PARAMN = 16;
    end;
    else if paramcd = "EXC11" then do;
param = "Subject has received medication within 14 days or within 5 half-lives of the drug prior to the Admission Day, which has an
impact on CYP1A2 or CYP2A6 activity."; paramn = 17; end;

    else if paramcd = "EXC12" then do;
        PARAM = "If a subject has received medication 14 days prior to screening/prior to admission day, it will be decided by the inve
stigator/designee if these can interfere with the study/subject's safety.";
        PARAMN = 18;
    end;
    else if paramcd = "EXC13" then do;
param = "Concomitant use of Nonsteroidal Anti Inflammatory Drugs (NSAIDs) or acetylsalicylic acid."; paramn = 19; end;
    else if paramcd = "EXC14" then do;
        PARAM = "The subject has a positive alcohol test and/or a history of alcohol abuse that could interfere with the subject's part
icipation in the study.";
        PARAMN = 20;
    end;
    else if paramcd = "EXC15" then do;
param = "The subject has a positive urine drug test.";
paramn = 21;
end;
    else if paramcd = "EXC16" then do;
param = "Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B surface antigen (HBSAG), or hepatitis C virus
(HCV).";
paramn = 22;
end;
    else if paramcd = "EXC17" then do;
param = "Donation or receipt of whole blood or blood products within 3 months prior to Admission.";
paramn = 23; end;
    else if paramcd = "EXC18" then do;
param = "The subject is a current or former employee of the tobacco industry or of their first-degree relatives (parent, sibling, or
child).";
paramn = 24; end;
    else if paramcd = "EXC19" then do;
param = "The subject is an employee of the investigational site or any other parties involved in the study or of their first-degree
relatives (parent, sibling, or child).";
paramn=25;
end;
    else if paramcd = "EXC20" then do;
param = "The subject has participated in a clinical study within 3 months prior to the Screening Visit.";
paramn=26; end;
    else if paramcd = "EXC21" then do;
param = "For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast fee
ding.";
paramn=27; end;
    else if paramcd = "EXC22" then do;
param = "For women only: Subject does not agree to use an acceptable method of effective contraception."; paramn=28; end;
    else put "WAR" "NING: Unexpected value " paramcd;
keep subject sitenumber paramcd parcat1 parcat1N avalc avisit avisitn param paramn;
run;
*****;
* bring in ADSL ;
*****;

data adsl;
    set adam.adsl;
/* keep studyid usubjid subjid: siteid age sex: race height weightbl bmi ucpdgr: */
/* scrffl saffl fasfl fsaffl nicogr: targr: randfl trtsdt trt01a trt01an trt01p trt01pn fupfl dthfl enfl exfl EXNOTRFL COMPLFL
*/
/*          pprot1f1 pprot2f1 pprot3f1 pprot4f1; */
run;
*****;
* Combine ADSL and IE data *;
*****;
/*proc sort data=adsl;by usubjid;run;*/
/*proc sort data=ie;by usubjid;run;*/
/* DATA SLIE;*/
/* * only include subject level data is eligibility issues */
/* MERGE ie(in=a) adsl ; */
/* BY USUBJID;*/
/* IF a;*/
/* run;*/

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/* data final;*/
/* length trtp trta $40 trtpn trtan aday 8 aperiod 8 aperiodc $10 ;*/
/* set slie;*/
/**/
/* aperiod=1;*/
/* if not missing(aperiod) then do;*/
/* aperiodc = 'Period ' || put(aperiod,1.);*/
/* end;*/
/**/
/*      if not missing(ADT) and not missing (TRTSDT) then ADAY = (ADT - TRTSDT) + 1;*/
/*      */
/*      if aperiod=1 then do;*/
/*      TRTP= TRT01p;*/
/*      TRTPN=trt01pn;*/
/*      TRTA=trt01a;*/
/*      trtan=trt01an;*/
/*      if missing (trt01a) then ;*/
/*      trta="";*/
/*/*      trt01an=.;*/
/* end;*/
/*RUN;*/
data sv;
  length subject $150 sitenumber 8;
set sdm.sv;

where visit in ('SCREENING' , 'DAY -2');
avisit =propcase(visit);

site=substr(usubjid,17,3);
subject=substr(usubjid,21,4);

if site='DAY' then sitenumber=31;
else if site='DAL' then sitenumber=29;
keep subject sitenumber avisit svstdtc visit;
run;
proc sort data=sv(keep= subject sitenumber avisit svstdtc );by subject sitenumber avisit;run;
proc sort data=ie;by subject sitenumber avisit;run;
DATA SvIE;
  length adt 8;
  MERGE ie(in=a) sv ;
BY subject sitenumber avisit;
if a;
adt= input(svstdtc,ymmdd10.);
format adt date9.;
run;
data s1;
length subject $150 sitenumber 8;
set adam.ads1;

if siteid='DAY' then sitenumber=31;
else if siteid='DAL' then sitenumber=29;
subject=substr(usubjid,21,4);

run;

*****;
* Combine ADSL and IE data *;
*****;
proc sort data=s1;by subject sitenumber;run;
proc sort data=svie;by subject sitenumber;run;

DATA SLIE;
  * only include subject level data is eligibilty issues ;
MERGE svie(in=a) s1 ;
BY subject sitenumber ;
IF a;
run;
data final;
length trtp trta $40 trtpn trtan aday 8 aperiod 8 aperiodc $10 ;
set slie;
aperiod=1;
if not missing(aperiod) then do;
  aperiodc = 'Period ' || put(aperiod,1.);
end;

      if not missing(ADT) and not missing (TRTSDT) then ADAY = (ADT - TRTSDT) + 1;

if aperiod=1 then do;

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    TRTP= TRT01p;
    TRTPN=trt01pn;
    TRTA=trt01a;
    trtan=trt01an;
/* if missing (trt01a) then ;*/
/*    trta="";*/
/*  trt01an=.;*/
end;

RUN;

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

data adel;
  set final;
  run;

%m_attrib_adam(dset=ADEL);

proc sort data = adel out = adam.adel(label = 'Eligibility Analysis Dataset');
  BY USUBJID AVISITN PARAMCD;
run;

%m_logchk;

proc datasets lib=work nolist memtype=data kill; quit;
*=====;
* END OF PROGRAM CODE ;
*=====;

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