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/*=====
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| Covance Study Number   : 000000106331          |
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```
| Program Name           : adcm.sas              |
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```
| Purpose                 : Create Adam Dataset (ADEL)      |
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```
| Input Data              : adsl ,sdtm.ie          |
```

```
| Output Data             : adma.adel             |   |
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|                          |
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| Macros Called           :                       |
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```
| Originally Performed by :paddepalli            |
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```
| Date                    : 13Mar2015            |
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| Modification History : Original Version          |
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| Modified by           :                       |
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| Modification Date      :                       |
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| Modification Reason    :                       |
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| Program Version        :                       |
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+=====
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```
proc datasets lib=work nolist memtype=data kill; quit;
```

```
libname adam "&base2/datasets/adam/cleaned_adam";
```

```

libname sdtm "/cvn/projects/prj/data/000000106331/datasets/sdtm/sdtmx";

%m_printto(route=YES);

options validvarname=upcase missing=' ';

*=====;

* START OF PROGRAM CODE                                ;

*=====;

*****;

* bring in IE from sdtm.ie ;

*****;

data ie_all;

set crf.ie_i crf.ie_i_adm crf.ie_i_sf crf.ie_e crf.ie_e_adm crf.ie_e_sf;

drop sitenumber;

rename siteid=sitenumber;

/*keep subject siteid;*/

run;

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;
```

```
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;
```

```
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;
```

```
if parcat1 = "INCLUSION" then parcat1n=1;
```

```
else parcat1n=2;
```

if PARAMCD = "INC01" then do;

PARAM = "Subject has signed the informed consent form (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 aged from 23 to 65 years (inclusive).";

PARAMN = 2;

end;

else if PARAMCD = "INC03" then do;

PARAM = "Subject is Japanese.";

PARAMN = 3;

end;

else if PARAMCD = "INC04" then do;

PARAM = "Smoking, healthy subject as judged by the Principal Investigator (PI) based on all available assessments in the Screening period / day of admission.";

PARAMN = 4;

end;

else if PARAMCD = "INC05" then do;

PARAM = "Subject smokes at least 10 commercially available CC per day (no brand restrictions) for the last 4 weeks, based on self-reporting and has been smoking for at least the last 3 consecutive years.";

PARAMN = 5;

end;

else if PARAMCD = "INC06" then do;

PARAM = "The subject does not plan to quit smoking in the next 3 months.";

```
PARAMN = 6;

end;

else if PARAMCD = "INC07" then do;

PARAM = "The subject is ready to accept interruptions of smoking for up to 5 days.";

PARAMN = 7;

end;

else if PARAMCD = "INC08" then do;

PARAM = "The subject is ready to accept using the THS 2.2.";

PARAMN = 8;

end;


else if PARAMCD = "EXC01" then do;

PARAM = "As per PI judgement, the subject cannot participate in the study for any reason.";

PARAMN = 9;

end;

else if PARAMCD = "EXC02" then do;

PARAM = "A subject who is legally incompetent, physically or mentally incapable of giving consent.";

PARAMN = 10;

end;

else if PARAMCD = "EXC03" then do;

PARAM = "The subject has medical condition requiring smoking cessation, or clinically relevant diseases
in the judgement of the PI.";

PARAMN = 11;

end;

else if PARAMCD = "EXC04" then do;

PARAM = "The subject has a body mass index (BMI) <18.5 or >= 32.0 kg/m2.";
```

PARAMN = 12;

end;

else if PARAMCD = "EXC05" then do;

PARAM = "The subject has medical conditions which require or will require in the course of the study a medical intervention which may interfere with the study participation and/or study results.";

PARAMN = 13;

end;

else if PARAMCD = "EXC06" then do;

PARAM = "The subject has used nicotine-containing products other than commercially available CC as well as electronic cigarettes and similar devices, within 4 weeks prior to assessment.";

PARAMN = 14;

end;

else if PARAMCD = "EXC07" then do;

PARAM = "The subject has received medication within 14 days or within 5 half-lives of the drug prior to the Admission Day that has an impact on CYP1A2 or CYP2A6 activity.";

PARAMN = 15;

end;

else if PARAMCD = "EXC08" then do;

PARAM = "In case subject received medication within 14 days prior to Screening/prior to Admission it will be decided by the PI if these can potentially interfere with the study objectives and subject's safety.";

PARAMN = 16;

end;

else if PARAMCD = "EXC09" then do;

PARAM = "Concomitant use of non-steroidal anti-inflammatory drugs (NSAIDS) or acetylsalicylic acid.";

PARAMN = 17;

end;

else if PARAMCD = "EXC10" then do;

PARAM = "The subject has a positive alcohol test and/or the subject has a history of alcohol abuse that could interfere with subject's participation in the study.";

PARAMN = 18;

end;

else if PARAMCD = "EXC11" then do;

PARAM = "The subject has a positive urine drug test.";

PARAMN = 19;

end;

else if PARAMCD = "EXC12" then do;

PARAM = "Positive serology test for human immunodeficiency virus (HIV)1/2, hepatitis B surface antigen (HbsAg), or hepatitis C virus (HCV).";

PARAMN = 20;

end;

else if PARAMCD = "EXC13" then do;

PARAM = "Donation or receipt of whole blood or blood products within 3 months prior to Admission.";

PARAMN = 21;

end;

else if PARAMCD = "EXC14" then do;

PARAM = "The subject is a former or current employee of the tobacco industry or of their first-degree relatives (parent, sibling or child).";

PARAMN = 22;

end;

else if PARAMCD = "EXC15" 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 = 23;

end;

else if PARAMCD = "EXC16" then do;

PARAM = "The subject has participated in a clinical study within 3 months prior to the Screening Visit.";

PARAMN = 24;

end;

else if PARAMCD = "EXC17" then do;

PARAM = "The subject has previously participated in the same study at a different time (i.e. each subject can be included in the study population only once).";

PARAMN = 25;

end;

else if PARAMCD = "EXC18" then do;

PARAM = "For women only: Subject is pregnant (does not have negative pregnancy tests at Screening and at Admission) or is breast feeding.";

PARAMN = 26;

end;

else if PARAMCD = "EXC19" then do;

PARAM = "For women only: Subject does not agree to use an acceptable method of effective contraception.";

PARAMN = 27;

end;

keep subject sitenumber paramcd parcat1 parcat1N avalc avisit avisitn param paramn;

run;

*****,

* bring in ADSL ;

*****,


```

data sv;

length subject $150 sitenumber 8;

set sdtm.sv;


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

avisit =propcase(visit);


site=substr(usubjid,17,3);

subject=substr(usubjid,21,4);


if site='TOK' then sitenumber=22;

else if site='SEI' then sitenumber=23;

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,yyymmdd10.);

format adt date9.;

run;

data sl;

```

```
length subject $150 sitenumber 8;
```

```
set adam.adsl;
```

```
if siteid='TOK' then sitenumber=22;
```

```
else if siteid='SEI' then sitenumber=23;
```

```
subject=substr(usubjid,21,4);
```

```
run;
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*****,
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```
* Combine ADSL and IE data *;
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*****,
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```
proc sort data=sl;by subject sitenumber;run;
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```
proc sort data=svie;by subject sitenumber;run;
```

```
DATA SLIE;
```

```
    * only include subject level data is eligibilty issues ;
```

```
    MERGE svie(in=a) sl ;
```

```
    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;

                TRTP= TRT01p;

                TRTPN=trt01pn;

                TRTA=trt01a;

                trtan=trt01an;

        end;

RUN;

*****;

* create output dataset ;

*****;

data adel;

set final;

run;

%m_logchk;

%m_attrib_adam(dset=ADEL);

```

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

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*=====;
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```
* END OF PROGRAM CODE                ;
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*=====;
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