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Purpose: To create DM SDTM CRT.

Program name: dm.sas

Input Programs: NA

Input Data Objects/Files: rd_dem,rd_inf1,ta.xpt

Output Data Objects/Files: dm.xpt, suppdm.xpt

Program Design:

- 1) Read input data
- 2) Process DM data
- 3) Select Variables, Change order, sort data and export domain DM
- 4) Create Supplemental Qualifiers for DM
- 5) Export SUPPDM data

Notes: This is one of the modules included in a _batch.sas program.

Version/Change history:

Date Author Description

13JUL2011 www.clinicalsasonlinelearning.weebly.com New Program

*****/

/*****

* (1) Read input data

*****/

/** Investigator Name **/

proc sql;

create table inv1 as select

b.SITEID as SITE_ID

, a.USERDISPLAYNAME

, a.USERNAME

, a.USERID

, catx(' ', USERFIRSTNAME, USERLASTNAME) as INVNAM

from io.irv_cur_user as a

left join io.irv_users_sites as b

on a.USERID=b.USERID and a.USERNAME = b.USERNAME

where (a.RIGHTSGROUP contains 'PI') and (b.RIGHTSGROUP contains 'PI')

```
order by SITEID, USERID;
```

```
quit;
```

```
proc sort data=io.irv_cur_subject out=irv_cur_subject (rename=(SITEID=SITE_ID));
```

```
by SITEID USERID;
```

```
run;
```

```
data inv2;
```

```
merge irv_cur_subject(in=a) inv1(in=b);
```

```
by SITE_ID USERID;
```

```
if b;
```

```
run;
```

```
proc sort data=inv2;
```

```
by SUBJECTNUMBERSTR SITE_ID;
```

```
run;
```

```
/** First infusion date **/
```

```
proc sort data=io.rd_inf1 out=infusion;
```

```
by SUBJECTNUMBERSTR VISITORORDER;
```

```
run;
```

```
data first_infusion;
```

```
set infusion;
```

```
if first.SUBJECTNUMBERSTR;
```

```
by SUBJECTNUMBERSTR VISITORORDER;
```

```
run;
```

```
proc sql;
```

```
***** Select Columns of Demographic;
```

```
create table DEMO1 as select
```

```
    '170903' as STUDYID label='Study Identifier' length=30 format $30.
```

```
    , 'DM' AS DOMAIN label='Domain Abbreviation' format=$2. length=2
```

```
    , catx('-', '170903', input(strip(a.SUBJECTNUMBERSTR),?6.)) as USUBJID
```

```
    label='Unique Subject Identifier' format=$50. length=50
```

```
    , a.SUBID as SUBJID label='Subject Identifier for the Study' format=$20. length=20
```

```
    , b.INFDATE_DTS as INFDATE
```

```
    , substr(a.SUBID,1,2) as SITEID label='Study Site Identifier' format=$200. length=200
```

```
    , tranwrd(a.YOB_DTS,'NUL', 'UNK') as BRTH_DT
```

```
    , . as AGE label='Age'
```

```
    , case
```

```
        when calculated AGE ne . then 'YEARS'
```

```

        else ''
    end as AGEU label='Age Units' format=$200. length=200
, case
    when a.SEX='Male' then 'M'
    when a.SEX='Female' then 'F'
end as SEX label='Sex' format=$200. length=200
,
upcase(catx(';',a.RACE_AMINDIAN,a.RACE_ASIAN,a.RACE_BLACKORAFRAM,a.RACE_HPACISLANDER,a.RACE_WHITE)) as NEWRACE
    'Newrace' format=$200. length=200
, upcase(a.RACE_AMINDIAN) as RACE1
, upcase(a.RACE_ASIAN) as RACE2
, upcase(a.RACE_BLACKORAFRAM) as RACE3
, upcase(a.RACE_HPACISLANDER) as RACE4
, upcase(a.RACE_WHITE) as RACE5
, case
    when index(calculated NEWRACE,';') gt 0 then 'MULTIPLE'
    else calculated NEWRACE
end as RACE 'Race' format=$200. length=200
, upcase(a.ETHNIC) as ETHNIC label='Ethnicity' format=$200. length=200
, a.SITECOUNTRY as COUNTRY label='Country' format=$200. length=200 informat=$200.
, input(substr(put(a.SCRNDAT,datetime.), 1,7), date9.) as SCRNDT format=yymmdd10.
, substr(put(a.SCRNDAT,datetime.),9,8) as SCRNTM
, put(a.age,best32.) as DMAGESC 'Age at Screening' format=$200. length=200
, case
    when a.age is not null then 'YEARS'

```

```

        else ""
    end as DMAGESCU 'Unit Age at Screening' format=$200. length=200
, case
    when upcase(a.PREVSCR) eq 'YES' then catx(':', 'Y', a.PRESUBID)
    when upcase(a.PREVSCR) eq 'NO' then 'N'
    else ""
end as PRESCRID label='Previously Screened' format=$200. length=200
, a.SITEID as SITE_ID
, a.SUBJECTNUMBERSTR
from io.rd_dem as a
left join first_infusion as b
on a.SUBJECTNUMBERSTR=b.SUBJECTNUMBERSTR
order by SUBJECTNUMBERSTR, SITE_ID;
quit;

/*****
(2) Process DM data
*****/

data demo2;

merge demo1 (in=a) inv2(in=b keep=SUBJECTNUMBERSTR SITE_ID USERDISPLAYNAME INVNAM);
by SUBJECTNUMBERSTR SITE_ID ;

if a;

SCRN_DT1=put(SCRN_DT,yymmdd10.);

```

```
run;
```

```
proc sort data=io.rd_mh3 out=rd_mh3;
```

```
  by SUBJECTNUMBERSTR;
```

```
run;
```

```
data demo3;
```

```
  merge demo2(in=a) rd_mh3(in=b keep=SUBJECTNUMBERSTR IGXTYP);
```

```
  by SUBJECTNUMBERSTR;
```

```
run;
```

```
data demo4;
```

```
  attrib RFSTDTC label= 'Subject Reference Start Date/Time' format=$65. length=$65
```

```
    RFENDTC label= 'Subject Reference End Date/Time' format=$65. length=$65
```

```
    DMDTC label= 'Date/Time of Collection' format=$65. length=$65
```

```
    BRTHDTC label= 'Date/Time of Birth' format=$65. length=$65
```

```
    DMDY label= 'Study Day of Collection' format=8. length=8
```

```
    ARM label= 'Description of Planned Arm' format=$200. length=$200
```

```
    ARMCD label= 'Planned Arm Code' format=$8. length=$8
```

```
    INVNAM label= 'Investigator Name' format=$200. length=$200 informat=$200.;
```

```
set demo3 ;
```

```
/** Assign ARM and ARMCD **/
```

```
if IGTXTYP = 'IV' then do;
```

```
    ARM = "IV-SC 20% Treatment" ;
```

```
    ARMCD = 'IVSC';
```

```
end;
```

```
if IGTXTYP = 'SC' then do;
```

```
    ARM = "SC-SC 20% Treatment" ;
```

```
    ARMCD = 'SCSC';
```

```
end;
```

```
/** Convert date and time information to ISO8601 format **/
```

```
%Char2ISO8601(dtc=INFDATE, isodttmc=RFSTDTC ) */;
```

```
%Char2ISO8601(dtc=INFDATE, isodttmc=RFENDTC ) */;
```

```
%Char2ISO8601(dtc=BIRTH_DT, isodttmc=BIRTHDTC ) */;
```

```
%Char2ISO8601(dtc=SCRN_DT1, tmc=SCRN_TM, isodttmc=DMDTC ) */;
```

```
/** Convert date values to numeric for calculation **/;
```

```
%ISO86012Num(RFSTDTC, dt=RFSTDTC);
```

```
%ISO86012Num(DMDTC, dt=DMDTN);
```

```
if DMDTC ne '' and RFSTDTC ne '' then do;
```

```
    if DMDTN < RFSTDN then DMDY=intck('day',RFSTDN,DMDTN);
```

```
    else DMDY=intck('day',RFSTDN,DMDTN)+1;
```

```
end;
```

```
run;
```

```
/******
```

```
* (3) Select Variables, Change order, sort data and export domain DM
```

```
*****/
```

```
proc sql;
```

```
    create table dm.dm(label='Demographics') as select
```

```
        STUDYID,
```

```
        DOMAIN,
```

```
        USUBJID,
```

```
        SUBJID,
```

```
        RFSTDTC,
```

```
        RFENDTC,
```

```
        SITEID,
```

```
        INVNAM,
```

```

    BRTHDTC,
    AGE,
    AGEU,
    SEX,
    RACE,
    ETHNIC,
    ARMCD,
    ARM,
    COUNTRY,
    DMDTC,
    DMDY
from demo4

order by USUBJID;

quit;

proc transpose data=DEMO4 out=race1(where=(col1 ne ' '));
    by subjid;
    var race1-race5;
run;

proc sql;
    create table race2 as select
        subjid,
        _NAME_ as racenumber,

```

```
        count(_NAME_) as answer
from race1
group by subjid ;
quit;

/* Multiple Races */
data race;

set race2;

if answer=1 then do;

    if racenumber='RACE1' then RACE_t='AMERICAN INDIAN OR ALASKA NATIVE';

    else if racenumber='RACE2' then RACE_t='ASIAN';

    else if racenumber='RACE3' then RACE_t='BLACK OR AFRICAN AMERICAN';

    else if racenumber='RACE4' then RACE_t='NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER';

    else if racenumber='RACE5' then RACE_t='WHITE';

end;

else if answer>1 then RACE_t='MULTIPLE';

run;

proc sort data=race2;

    by SUBJID RACENUMBER;

run;
```

```
data mult_races;
```

```
  set race2;
```

```
  where answer>1;
```

```
  by subjid;
```

```
  retain i;
```

```
  if first.subjid then i=1;
```

```
  else i+1;
```

```
run;
```

```
proc sort data=demo4;
```

```
  by STUDYID USUBJID;
```

```
run;
```

```
proc transpose data=demo4 out=trans_demo4 (rename=( _NAME_=QNAM _LABEL_=QLABEL  
COL1=QVAL));;
```

```
  by STUDYID USUBJID;
```

```
  var DMAGESC DMAGESCU PRESCRID ;
```

```
run;
```

```
data suppdm1;
```

```
  attrib RDOMAIN label='Related Domain Abbreviation' format=$2.
```

```
  IDVAR label='Identifying Variable' format=$8.
```

```
  IDVARVAL label='Identifying Variable Value' format=$200.
```

QNAM label='Qualifier Variable Name' format=\$8.
QLABEL label='Qualifier Variable Label' format=\$40.
QVAL label='Data Value' format=\$200.
QORIG label='Origin' format=\$20.
QEVAL label='Evaluator' format=\$100.;

set trans_demo4;

RDOMAIN = 'DM';
IDVAR = ' ';
IDVARVAL= ' ';
QEVAL=' ';
QORIG='CRF';
QVAL=trim(left(QVAL));

where trim(left(QVAL)) not in ('.', '');

run;

```
/******  
***  
  
* (5) Export SUPPDM data  
  
*****  
**/
```

proc sql;

```
create table suppdm2 as select
```

```
    STUDYID ,
```

```
    RDOMAIN ,
```

```
    USUBJID ,
```

```
    IDVAR,
```

```
    IDVARVAL,
```

```
    QNAM,
```

```
    QLABEL,
```

```
    QVAL,
```

```
    QORIG,
```

```
    QEVAL
```

```
from suppdm1
```

```
order by USUBJID;
```

```
/*Multiple Races*/
```

```
insert into suppdm2 select
```

```
'170903',
```

```
'DM',
```

```
cats('170903-', SUBJID),
```

```
'' ,
```

```
'' ,
```

```
cats('RACE',put(i,1.)),
```

```
cats('Race ',put(i,1.)),
```

```
case
```

```
    when racenumber='RACE1' then 'AMERICAN INDIAN OR ALASKA NATIVE'
```

```
when racenumber='RACE2' then 'ASIAN'

when racenumber='RACE3' then 'BLACK OR AFRICAN AMERICAN'

when racenumber='RACE4' then 'NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER'

when racenumber='RACE5' then 'WHITE'

else ''

end,

'CRF',

''

from mult_races;

quit;

proc sort data=suppdm2 out=suppdm.suppdm(label='Supplemental Qualifiers for DM');

by USUBJID QNAM;

where QVAL ne "";

run;
```