How to Create SDTM DM SAS Transport Datasets using Python

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ABSTRACT

The paper is written for those who wants to use Python to create SDTM SAS transport files from Raw SAS datasets. The paper will show the similarity and differences between SAS and Python in terms of SDTM dataset development, and actual Python codes to create SDTM SAS transport file.

The paper will start with Python packages that could read and write SAS datasets such as xport, sas7bdat, and pyreadstat. The paper will introduce how Python reads SAS datasets from the local drive such as demographic, exposure, randomization and disposition raw SAS datasets. The paper will also show how Python creates variables from raw data such as SEX, USUBJID, RACE, RFSTDTC, and RFENDTC. The paper will also show how Python merge datasets using outer and inner join. The paper will also show how programmers use Python Dataframe for data manipulation such as renaming, dropping, and replacing variables. Finally, the paper will show how Python could create SAS SDTM transport file in the local drive.

The paper also includes the actual python codes that read Raw SAS datasets, merge, manipulate and write SDTM DM SAS xport file.

Download the required Python packages

SAS programmers need to download xport packages.
pip install xport==2.0.2 on “Anaconda Prompt” command line. Please note that SAS programmers need to download version 2.0.2. The latest version does not work properly.

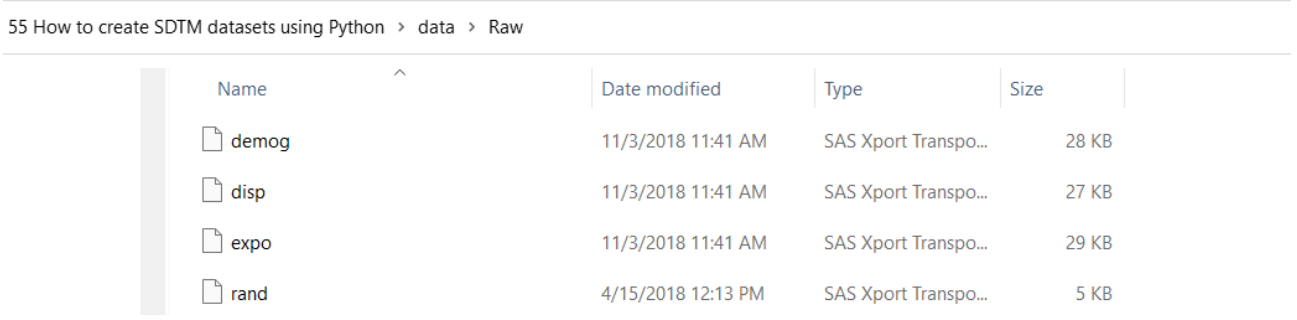
Import required python package

In order to read and write SAS datasets, the programmers need to import xport. There are other SAS packages such as sas7bdat and pyreadstat, but the programmers can't write transport SAS datasets using other packages.

In [1]:
```
### Import modules
from pandas import Series, DataFrame
import pandas as pd
import xport  ## write sas datasets to local drive
```

Importing RAW SAS Datasets

First, the programmers need to read SAS Xport dataset from the local drive. Below is the location of SAS Raw Data.



Prepare demog datasets

SAS programmers read the transport SAS dataset of demog.xpt into DataFrame, which is the most popular Python tablular dataset.

In [2]:
```
### Read Raw demog SAS datasets
with open('./data/raw/demog.xpt', 'rb') as f:
```

```
    df_dm = xport.to_columns(f)
    df_dm2 = pd.DataFrame(df_dm)
```

In [3]:
```
df_dm2.head()  ## Show the first 5 records.
```

Out[3]:

	AGE	AGEU	RACEC	SITEID	STUDYID	SUBJID	SEXC
0	63.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1015	Female
1	64.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1023	Male
2	71.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1028	Male
3	74.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1033	Male
4	77.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1034	Female

SAS programmers can create SDTM variales using replace method. Below SAS codes are equivalent to the provided Python codes.

```
DATA dm2;
  set dm2;

  if SEXC = 'Male' then SEX = 'M';
  else if SEXC = 'Femail' then SEX = 'F';

  DOMAIN = 'DM';
  COUNTRY = 'USA';

  USUBJID = STUDYID + '-' + 'SITEID' + '-' + SUBJID ;

RUN;
```

In [4]:
```
### Prepare variables
df_dm2['SEX'] = df_dm2.SEXC.replace(['Male','Female'], ['M','F']) # Create SEX variable
df_dm2['DOMAIN'], df_dm2['COUNTRY'] = 'DM', 'USA' # Create varialbes DOMAIN & COUNTRY
df_dm2['USUBJID'] = df_dm2.STUDYID + '-' + df_dm2.SITEID + '-' + df_dm2.SUBJID  # create USUBJID
df_dm2.head()
```

Out[4]:

	AGE	AGEU	RACEC	SITEID	STUDYID	SUBJID	SEXC	SEX	DOMAIN	COUNTRY	USUBJID
0	63.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1015	Female	F	DM	USA	CDISCPILOT01-701-1015
1	64.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1023	Male	M	DM	USA	CDISCPILOT01-701-1023
2	71.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1028	Male	M	DM	USA	CDISCPILOT01-701-1028
3	74.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1033	Male	M	DM	USA	CDISCPILOT01-701-1033
4	77.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1034	Female	F	DM	USA	CDISCPILOT01-701-1034

SAS programmers also can use the iteration of Data Frame to create Series to update each variable. Below SAS codes are equivalent to provided Python codes.

```
DATA dm2;
  set dm2;

  if index(RACEC, 'HISPANIC') > 0 then ETHNIC = 'HISPANIC OR LATINO';
  else ETHNIC = 'NOT HISPANIC OR LATINO';

  if index(RACEC, 'HISPANIC') > 0 then RACE = 'WHITE';
```

```
else if index(RACEC, 'CAUCASIAN') > 0 then RACE = 'WHITE';
else if index(RACEC, 'AFRICAN') > 0 then RACE = 'BLACK';

RUN;
```

In [5]:

```
for index, _df1 in df_dm2.iterrows():
    ## Create Ethnic
    if _df1['RACEC'].__contains__('HISPANIC'):
        df_dm2.loc[index, 'ETHNIC'] = 'HISPANIC OR LATINO'
    else:
        df_dm2.loc[index, 'ETHNIC'] = 'NOT HISPANIC OR LATINO'

    ## Create Race
    if _df1['RACEC'].__contains__('HISPANIC'):
        df_dm2.loc[index, 'RACE'] = 'WHITE'
    elif _df1['RACEC'].__contains__('CAUCASIAN'):
        df_dm2.loc[index, 'RACE'] = 'WHITE'
    elif _df1['RACEC'].__contains__('AFRICAN'):
        df_dm2.loc[index, 'RACE'] = 'BLACK'
    elif _df1['RACEC'].__contains__('OTHER'):
        df_dm2.loc[index, 'RACE'] = 'OTHER'

df_dm2.head()
```

Out[5]:

	AGE	AGEU	RACEC	SITEID	STUDYID	SUBJID	SEXC	SEX	DOMAIN	COUNTRY	USUBJID	ETHNIC	RACE
0	63.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1015	Female	F	DM	USA	CDISCPILOT01-701-1015	HISPANIC OR LATINO	WHITE
1	64.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1023	Male	M	DM	USA	CDISCPILOT01-701-1023	HISPANIC OR LATINO	WHITE
2	71.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1028	Male	M	DM	USA	CDISCPILOT01-701-1028	NOT HISPANIC OR LATINO	WHITE
3	74.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1033	Male	M	DM	USA	CDISCPILOT01-701-1033	NOT HISPANIC OR LATINO	WHITE
4	77.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1034	Female	F	DM	USA	CDISCPILOT01-701-1034	NOT HISPANIC OR LATINO	WHITE

Prepare Exposure dataset

In [6]:

```
### Read exposure datasets
with open('./data/raw/expo.xpt', 'rb') as f:
    df_ex = xport.to_columns(f)
    df_ex2 = pd.DataFrame(df_ex)
df_ex2
```

Out[6]:

	SUBJID	EXDOSE	EXDOSU	EXSTDD	EXSTMM	EXSTYY	EXENDD	EXENMM	EXENYY	VISIT	VISITN
0	1015	0.0	mg	2014	01	02	2014	01	16	BASELINE	3.0
1	1015	0.0	mg	2014	01	17	2014	06	18	WEEK 2	4.0
2	1015	0.0	mg	2014	06	19	2014	07	02	WEEK 24	12.0
3	1023	0.0	mg	2012	08	05	2012	08	27	BASELINE	3.0
4	1023	0.0	mg	2012	08	28	2012	09	01	WEEK 2	4.0

	SUBJID	EXDOSE	EXDOSU	EXSTDD	EXSTMM	EXSTYY	EXENDD	EXENMM	EXENYY	VISIT	VISITN
...	...	...	...	...	...	...	...	...	...	...	...
586	1355	0.0	mg	2013	08	16	2013	08	29	WEEK 24	12.0
587	1371	54.0	mg	2013	04	26	2013	05	08	BASELINE	3.0
588	1371	81.0	mg	2013	05	09	2013	08	01	WEEK 2	4.0
589	1427	54.0	mg	2012	12	17	2012	12	31	BASELINE	3.0
590	1427	81.0	mg	2013	01	01	2013	02	11	WEEK 2	4.0

591 rows × 11 columns

In [7]:
```
### Prepare exposure variables
df_ex2['EXSTDTC'] = df_ex2['EXSTDD'] + '-' + df_ex2['EXSTMM'] + '-' + df_ex2['EXSTYY']  # exposure start date
df_ex2['EXENDTC'] = df_ex2['EXENDD'] + '-' + df_ex2['EXENMM'] + '-' + df_ex2['EXENYY']  # exposure end date
```

SAS programmers could use groupby and first method to pick the first exposure of subject. Below SAS codes are equivalent to the provided Python codes.

```
PROC SORT data = ex2 ; by SUBJID EXSTDTC ; RUN;
DATA ex4;
  set ex2;
  by SUBJID;

  if first.SUBJID;
RUN;
```

In [7]:
```
### Find the first and last exposure date
df_ex4 = df_ex2.sort_values(by =['SUBJID','EXSTDTC'], ascending=[True, True] )  # sort by subjid and expo date
df_ex4_f = df_ex4.groupby('SUBJID').first()  # pick the first exposure date of the subject
df_ex4_f2 = df_ex4_f.reset_index()  # reset index so that SUBJID become a variable.
```

SAS programmers could rename the variables.

```
DATA ex4_f;
  set ex4;
  rename
  EXSTDTC = RFSTDTC;
RUN;
```

In [7]:
```
## Rename the variables
df_ex4_f3 = df_ex4_f2[['SUBJID','EXSTDTC']].rename(columns={'EXSTDTC':'RFSTDTC'})  # select and rename variables
```

In [7]:
```
df_ex4_l = df_ex4.groupby('SUBJID').last()  # pick the last exposure date of the subject
df_ex4_l2 = df_ex4_l.reset_index()  # reset index so that SUBJID is column
df_ex4_l3 = df_ex4_l2[['SUBJID','EXENDTC']].rename(columns={'EXENDTC':'RFENDTC'})  # select and rename variables
```

In [8]:
```
df_ex4_f3.head()
```

Out[8]:

	SUBJID	RFSTDTC
0	1001	2013-10-08
1	1002	2014-01-14
2	1004	2014-01-14
3	1006	2013-02-10
4	1007	2012-07-31

In [9]:
```
df_ex4_l3.head()
```

Out[9]:

	SUBJID	RFENDTC
0	1001	2014-04-08
1	1002	2014-01-18
2	1004	2014-07-16
3	1006	2013-08-09
4	1007	2012-08-28

Merge exposure data

SAS programmers could merge two datasets. Below SAS codes are equivalent to the provided Python codes.

DATA ex5;
  merge ex4_f(in=a) ex4*l(in=b*;
  by SUBJID;
  if a and b;
RUN;

In [10]:
```
### merge first and last exposure date
df_ex5 = pd.merge(df_ex4_f3, df_ex4_l3, on='SUBJID')

### merge exposure data to demog data
df_dm3 = pd.merge(df_dm2, df_ex5, on='SUBJID', how='left')  # merge exposure information to dm
```

In [11]:
```
df_dm3.head()
```

Out[11]:

	AGE	AGEU	RACEC	SITEID	STUDYID	SUBJID	SEXC	SEX	DOMAIN	COUNTRY	USUBJID	ETHNIC	RACE	RFS
0	63.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1015	Female	F	DM	USA	CDISCPILOT01-701-1015	HISPANIC OR LATINO	WHITE	201
1	64.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1023	Male	M	DM	USA	CDISCPILOT01-701-1023	HISPANIC OR LATINO	WHITE	201
2	71.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1028	Male	M	DM	USA	CDISCPILOT01-701-1028	NOT HISPANIC OR LATINO	WHITE	201
3	74.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1033	Male	M	DM	USA	CDISCPILOT01-701-1033	NOT HISPANIC OR LATINO	WHITE	201
4	77.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1034	Female	F	DM	USA	CDISCPILOT01-701-1034	NOT HISPANIC OR LATINO	WHITE	201

Prepare Randomization data

In [12]:
```
### Read SAS datasets from the local drive
with open('./data/raw/rand.xpt', 'rb') as f:
```

```
    df_rm = xport.to_columns(f)
    df_rm2 = pd.DataFrame(df_rm)
```

merge randomization data to demog data

In [13]:
```
### Merge(inner join) randomization with demo by SUBJID.
df_dm4 = pd.merge(df_dm3, df_rm2, on='SUBJID', how='left')
df_dm4['ARM'] = df_dm4.DRUG
df_dm4['ARMCD'] = df_dm4.ARM.replace(['Control','Study Drug'], ['C','SD'])
df_dm4['ACTARMCD'] = df_dm4.ARMCD
df_dm4['ACTARM'] = df_dm4.ARM
```

In [14]:
```
df_dm4.head()
```

Out[14]:

	AGE	AGEU	RACEC	SITEID	STUDYID	SUBJID	SEXC	SEX	DOMAIN	COUNTRY	USUBJID	ETHNIC	RACE	RFS
0	63.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1015	Female	F	DM	USA	CDISCPILOT01-701-1015	HISPANIC OR LATINO	WHITE	201
1	64.0	YEARS	HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...	701	CDISCPILOT01	1023	Male	M	DM	USA	CDISCPILOT01-701-1023	HISPANIC OR LATINO	WHITE	201
2	71.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1028	Male	M	DM	USA	CDISCPILOT01-701-1028	NOT HISPANIC OR LATINO	WHITE	201
3	74.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1033	Male	M	DM	USA	CDISCPILOT01-701-1033	NOT HISPANIC OR LATINO	WHITE	201
4	77.0	YEARS	CAUCASIAN	701	CDISCPILOT01	1034	Female	F	DM	USA	CDISCPILOT01-701-1034	NOT HISPANIC OR LATINO	WHITE	201

Prepare Dispostion data

In [15]:
```
### Read disposition datasets from the local drive
with open('./data/raw/disp.xpt', 'rb') as f:
    df_ds = xport.to_columns(f)
    df_ds2 = pd.DataFrame(df_ds)
```

In [16]:
```
### Prepare dispostion data
df_ds2['DSSTDTC'] =   df_ds2['DSSTDD'] + '-' + df_ds2['DSSTMM'] + '-' + df_ds2['DSSTYY']  # dispostion date

### prepare death data
for index3, _df3 in df_ds2.iterrows():
    if _df3.DISP == 'DEATH':
        df_ds2.loc[index3, 'DTHDTC'] = _df3.DSSTDTC
        df_ds2.loc[index3, 'DTHFL'] = 'Y'

df_ds2['RFPENDTC'] = df_ds2.DSSTDTC
df_ds4 = df_ds2[['SUBJID', 'RFPENDTC', 'DTHFL', 'DTHDTC']]
```

Merge dispostion data to demog data

In [17]:
```
df_dm5 = pd.merge(df_dm4, df_ds4, on='SUBJID', how='left')
print(df_dm5.head())
```

```
    AGE   AGEU                                              RACEC SITEID  \
0  63.0  YEARS  HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...    701
1  64.0  YEARS  HISPANIC (MEXICAN - AMERICAN, MEXICO, CENTRAL ...    701
2  71.0  YEARS                                          CAUCASIAN    701
3  74.0  YEARS                                          CAUCASIAN    701
4  77.0  YEARS                                          CAUCASIAN    701

        STUDYID SUBJID    SEXC SEX DOMAIN COUNTRY  ...     RFSTDTC  \
0  CDISCPILOT01   1015  Female   F     DM     USA  ...  2014-01-02
1  CDISCPILOT01   1023    Male   M     DM     USA  ...  2012-08-05
2  CDISCPILOT01   1028    Male   M     DM     USA  ...  2013-07-19
3  CDISCPILOT01   1033    Male   M     DM     USA  ...  2014-03-18
4  CDISCPILOT01   1034  Female   F     DM     USA  ...  2014-07-01

      RFENDTC        DRUG         ARM ARMCD ACTARMCD      ACTARM    RFPENDTC  \
0  2014-07-02  Study Drug  Study Drug    SD       SD  Study Drug  2014-07-02
1  2012-09-01     Control     Control     C        C     Control  2012-09-02
2  2014-01-14     Control     Control     C        C     Control  2014-01-14
3  2014-03-31  Study Drug  Study Drug    SD       SD  Study Drug  2014-04-14
4  2014-12-30  Study Drug  Study Drug    SD       SD  Study Drug  2014-12-30

  DTHFL DTHDTC
0   NaN    NaN
1   NaN    NaN
2   NaN    NaN
3   NaN    NaN
4   NaN    NaN

[5 rows x 23 columns]
```

In [18]:

```
### Prepare demographic data
df_dm6 = df_dm5.drop(columns=['SEXC','RACEC','DRUG'])  # Drop variables
df_dm6['RFXSTTDTC'], df_dm6['RFSENDTC'], df_dm6['RFICDTC'] = df_dm6.RFSTDTC, df_dm6.RFENDTC, ''  ## Assign the va
```

In [19]:

```
df_dm6.head()
```

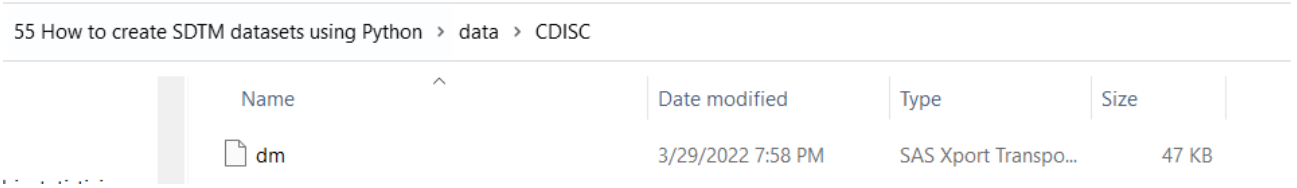
Out[19]:

	AGE	AGEU	SITEID	STUDYID	SUBJID	SEX	DOMAIN	COUNTRY	USUBJID	ETHNIC	...	ARM	ARMCD	ACTARMCD
0	63.0	YEARS	701	CDISCPILOT01	1015	F	DM	USA	CDISCPILOT01-701-1015	HISPANIC OR LATINO	...	Study Drug	SD	SD
1	64.0	YEARS	701	CDISCPILOT01	1023	M	DM	USA	CDISCPILOT01-701-1023	HISPANIC OR LATINO	...	Control	C	C
2	71.0	YEARS	701	CDISCPILOT01	1028	M	DM	USA	CDISCPILOT01-701-1028	NOT HISPANIC OR LATINO	...	Control	C	C
3	74.0	YEARS	701	CDISCPILOT01	1033	M	DM	USA	CDISCPILOT01-701-1033	NOT HISPANIC OR LATINO	...	Study Drug	SD	SD
4	77.0	YEARS	701	CDISCPILOT01	1034	F	DM	USA	CDISCPILOT01-701-1034	NOT HISPANIC OR LATINO	...	Study Drug	SD	SD

5 rows × 23 columns

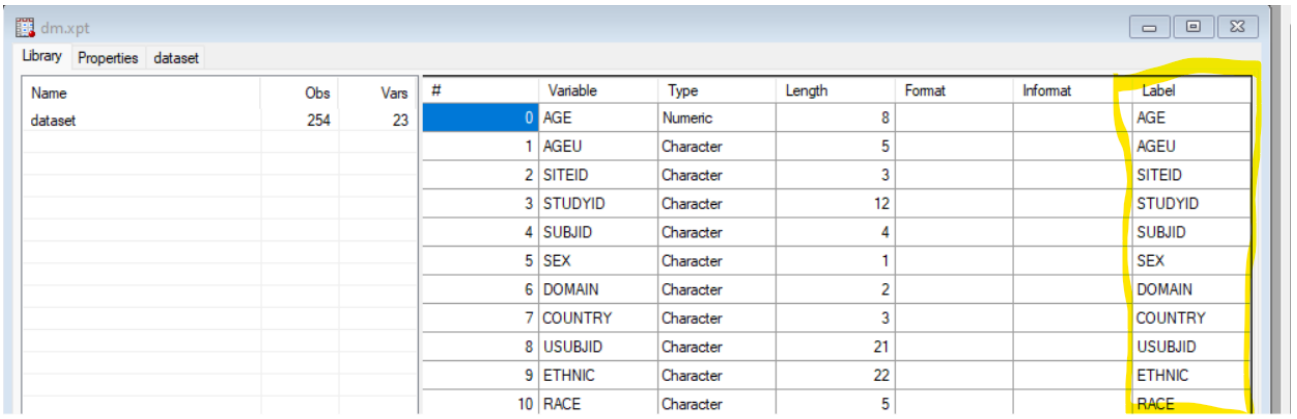
Write CDISC DM dataset

SAS programmers could write SAS xport into the local drive using xport function.



In [20]:
```
with open('./data/cdisc/dm.xpt', 'wb') as f:
    xport.from_dataframe(df_dm6, f)## write DM
```

One disdavantage using Python to create SAS Transport file is that the programmer won't be able to add the labels.



Conclusion

Programmers could create SDTM Dataset using Python just like SAS and R. Python could read SAS datasets, manipulate data, and write SAS dataset using SAS specific library. It would open more opportunities for programmers to learn new language such as Python and apply it in the clinical trial setting.

Reference

https://github.com/kevinlee1004/SDTM_DM_creation_using_python Github for "How to create SDTM SAS Transport datasets using Python"

CONTACT INFORMATION

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