CREATING SIMPLIFIED TS.XPT FILES

June 2019

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1. BACKGROUND

This guide is intended to help sponsors create Simplified TS Files (ts.xpt) to meet study data submission requirements to the Food & Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

Simplified TS Files provide a Study Start Date for NDA/BLA/ANDA studies that began on or before December 17, 2016 and Commercial IND studies that began on or before December 17, 2017 and allow FDA to determine that study data is not required to be in a CDISC standardized format. For additional information on FDA's study data submission requirements, please see the Technical Rejection Criteria for Study Data and the Study Data Technical Conformance Guide.

Simplified TS Files are SAS Transport files which can be created using free and open-source software, including Python and R.

Option 1 provides information to install R and R code to create a Simplified TS File using two different R packages. Steps to install both packages are provided. You will have to make simple edits to the code to provide details of the study.

Option 2 provides information to install Python and Python code to create a Simplified TS File. You will have to make simple edits to the code to provide details of the study, such as Study ID and Study Start Date. To create SAS Transport files in Python, the Xport module must first be installed. Steps to install the module are also provided.
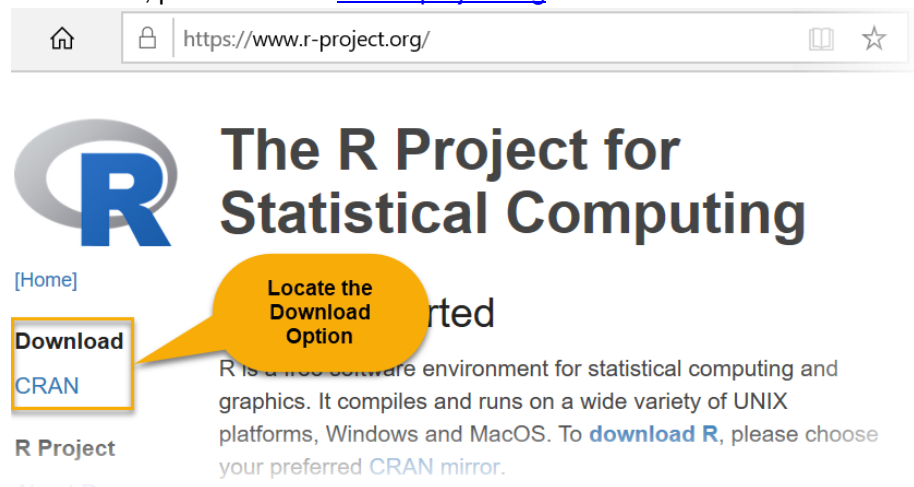
The final section provides details on how to install and use SAS Universal Viewer to review the Simplified TS Files you create.

2. CREATE SIMPLIFIED TS.XPT FILES
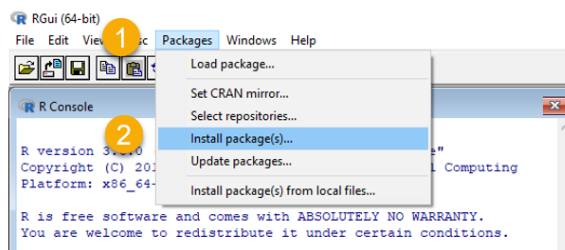
a) Option 1: Use R

i) Pre-Requisite: Install R

To install R, please refer to www.r-project.org and follow the installation instructions.
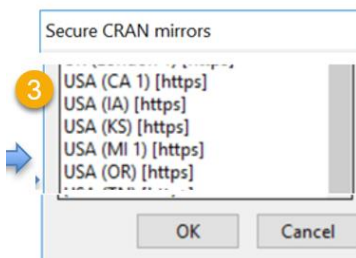
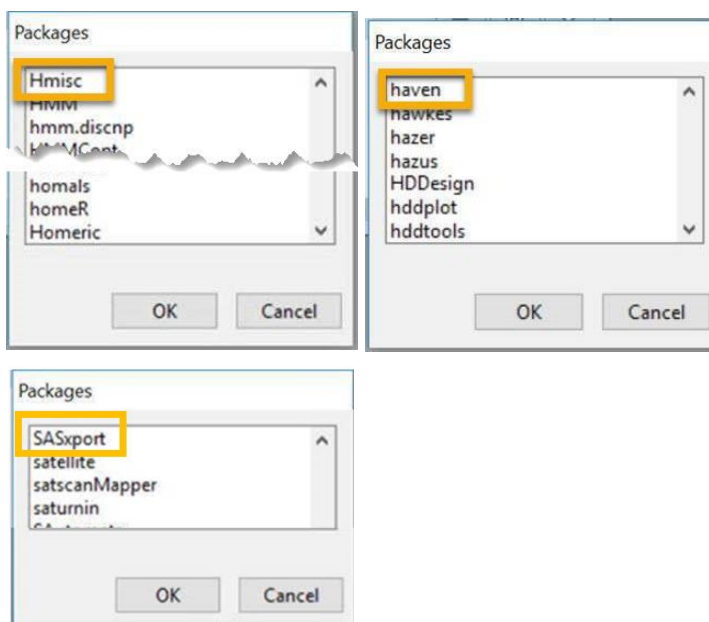Once you have installed R, open the R application and Install R packages.

1. Select the "Packages" menu
2. Select "Install Package(s)"

3. Select a CRAN Mirror.
   Note: You may select any CRAN mirror, but it is recommended that you select one close to your geographical proximity.
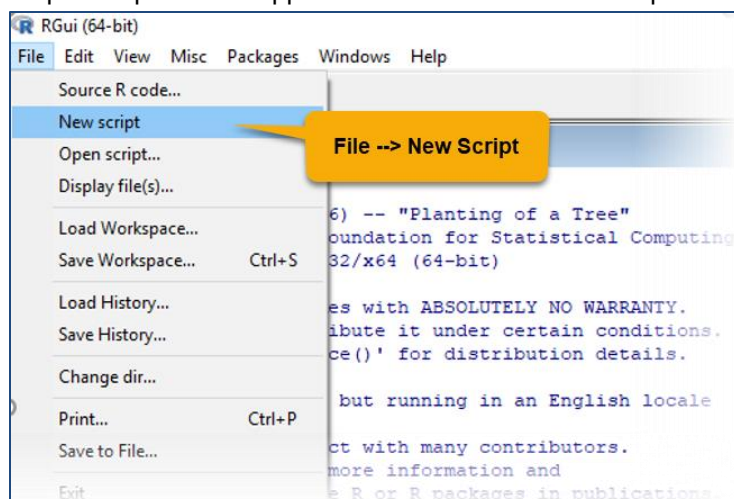
4. Install "Hmisc" and either "haven" or "SASxport."

ii) Create Simplified TS.xpt Using R

Step 1 – Open the R application and create a New script file

Step 2 – In the R Editor window, copy and paste the applicable code from Table 1, depending on the type of study and which R package you are using:

Table 1: Code for Creating TS.xpt Using R

R Package	Clinical Study	Non-clinical Study
Using the Haven Package – Option A	##Load Packages## Library (haven) Library (Hmisc) ##Create data file## data<-data.frame(STUDYID="XYZ123", 　　　　　　TSPSRMCD="SSTDTC", 　　　　　　TSVAL=strftime(as.Date("YYYY-MM-DD"),"%Y-%m-%d"), 　　　　　　TSVALNF=" ", 　　　　　　stringAsFactors=FALSE) ##Add data label and variable labels## label (data) <-'Trial Summary' label (data[['STUDYID']]) <-'Study Identifier' label (data[['TSPARMCD']]) <-'Trial Summary Parameter Short Name' label(data[['TSVAL']]) <-'Parameter Value' label (data[['TSVALNF']]) <-'Parameter Null Flavor' ##Write data into xpt format## write_xpt (data, path="C:/Simplified TS File/ts.xpt", version=5)	##Load Packages## Library (haven) Library (Hmisc) ##Create data file## data<-data.frame(STUDYID="XYZ123", 　　　　　　TSPARMCD="STSTDTC", 　　　　　　TSVAL=strftime(as.Date("YYYY-MM-DD"),"%Y-%m-%d"), 　　　　　　TSVALNF=" ", 　　　　　　stringAsFactors=FALSE) ##Add data label and variable labels## label (data) <-'Trial Summary' label (data[['STUDYID']]) <-'Study Identifier' label (data[['TSPARMCD']]) <-'Trial Summary Parameter Short Name' label(data[['TSVAL']]) <-'Parameter Value' label (data[['TSVALNF']]) <-'Parameter Null Flavor' ##Write data into xpt format## write_xpt (data, path="C:/Simplified TS File/ts.xpt", version=5)
Using the SASxport Package – Option B	##Load Package## Library (SASxport) Library (Hmisc) ##Create data file## abc<-data.frame(STUDYID="XYZ123", 　　　　　TSPSRMCD="SSTDTC", 　　　　　TSVAL=strftime(as.Date("YYYY-MM-DD"),"%Y-%m-%d"), 　　　　　TSVALNF=" ",	##Load Package## Library (SASxport) Library (Hmisc) ##Create data file## abc<-data.frame(STUDYID="XYZ123", 　　　　　TSPSRMCD="STSTDTC", 　　　　　TSVAL=strftime(as.Date("YYYY-MM-DD"),"%Y-%m-%d"), 　　　　　TSVALNF=" ",

stringAsFactors=FALSE) ##Add data label and variable labels## label (abc) <-'Trial Summary' label (abc$STUDYID) <-'Study Identifier' label (abc$TSPARMCD)<-'Trial Summary Parameter Short Name' label (abc$TSVAL) <-'Parameter Value' label (abc$TSVALNF) <-'Parameter Null Flavor' ##Write data into xpt format## write_xport (abc, file="C:/Simplified TS File/ts.xpt")	stringAsFactors=FALSE) ##Add data label and variable labels## label (abc) <-'Trial Summary' label (abc$STUDYID) <-'Study Identifier' label (abc$TSPARMCD) <-'Trial Summary Parameter Short Name' label (abc$TSVAL) <-'Parameter Value' label (abc$TSVALNF) <-'Parameter Null Flavor' ##Write data into xpt format## write_xport (abc, file="C:/Simplified TS File/ts.xpt")

Step 3 – After copying and pasting the code into the script editor, modify the code with your study parameters as follows:

1. Next to STUDYID, replace "XYZ123" with the applicable Study ID
2. Next to TSVAL, replace "YYYY-MM-DD" with the applicable study start date
3. If no Study Start Date is available, delete "YYYY-MM-DD", keeping the quotation marks, and next to "TSVALNF", enter a valid Study Start Date Exception Code

4. The file path, i.e. where the Simplified TS File will be saved, can be changed to your preferred location by replacing "C:/Simplified TS File/" with a different location

- **Note:** While editing Study ID, TSVAL, and TSVALNF, keep the quotation marks around the values you enter
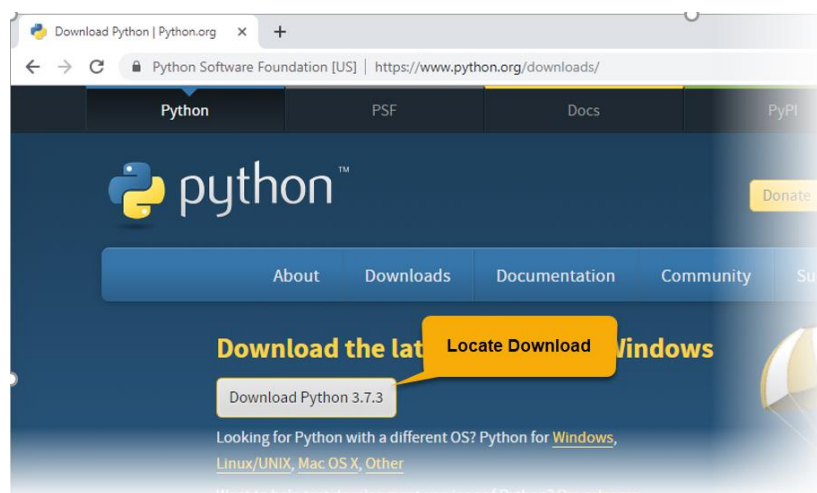
Step 4 – After updating the code, run the code by selecting run all from the Edit Menu. A Simplified TS File in .xpt format will be saved in the folder C:/Simplified TS File or the location you provided.
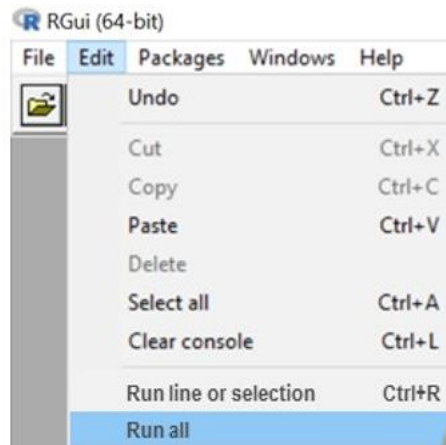
b) Option 2: Use Python

i) Pre-Requisite: Install Python and IDLE

To install Python and IDLE, please refer to www.python.org/downloads and follow installation instructions

IDLE is Python's Integrated Development and Learning Environment, also referred to as the Python Shell

To install the Xport module in Python please refer to https://pypi.org/project/xport/

1. At the CMD.exe command line interface, type in the following command and press ENTER:
   ```
   cd C:\Program
   Files\Python37\Scripts
   ```
2. Type in: python -m pip install -- upgrade pip (to ensure pip is at the latest version)
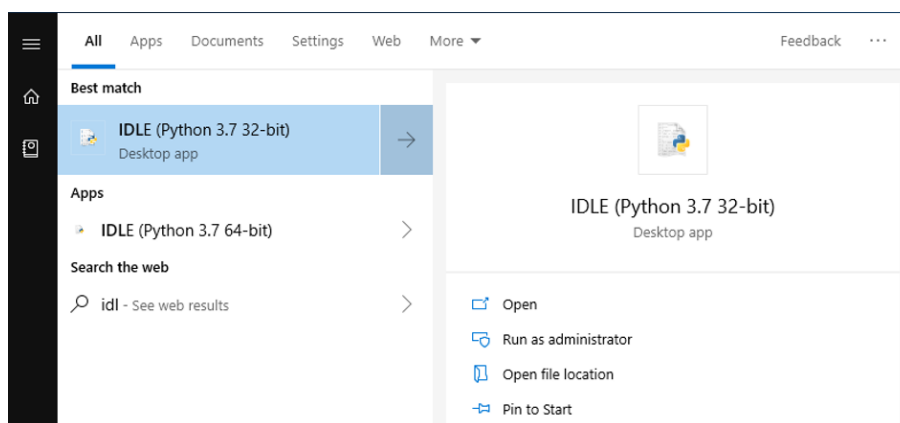3. Type in: pip install xport (to install the xport module)

ii) Create Simplified TS.xpt Using Python

Create a Simplified TS File in Python with the following steps:

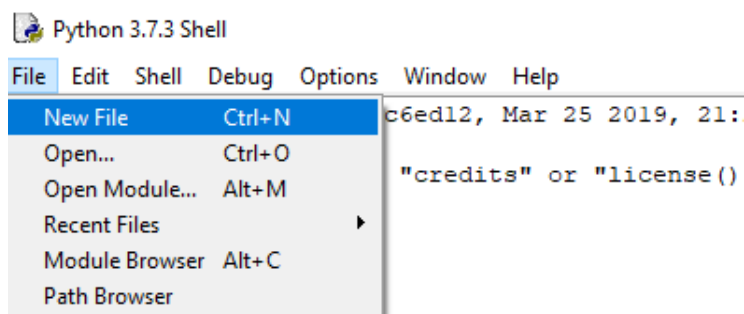Step 1 – Create a Folder in C Drive and name it as "Simplified TS File"
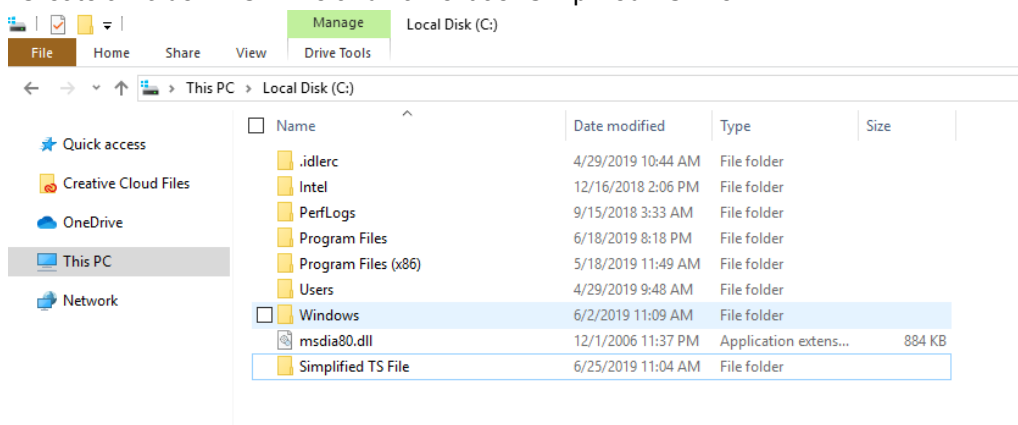
Step 2 – Open the IDLE application

Step 3 – Create New File

- File → New File

Step 4 – Paste the Python code and save the file with any file name, e.g. "Python Code for Simplified TS"

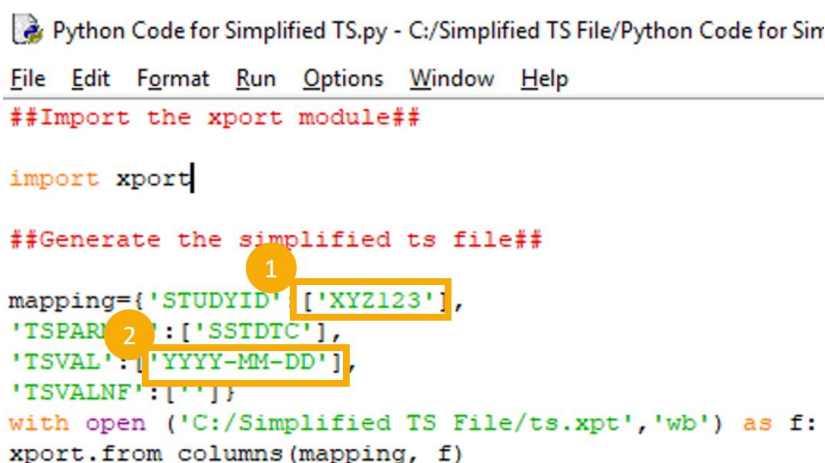- Paste the Python Code exactly as shown in Table 2.

Table 2: Code for Creating TS.xpt Using Python

Step	Clinical Study	Non-clinical Study
Step 1 - Import the xport module	##Import the xport module## import xport	##Import the xport module## import xport
Step 2 - Generate the simplified ts file	##Generate the simplified ts file## mapping={'STUDYID':['XYZ123'], 'TSPARMCD':['SSTDTC'], 'TSVAL':['YYYY-MM-DD'], 'TSVALNF':['']} with open ('C:/Simplified TS File/ts.xpt','wb') as f: xport.from_columns(mapping, f)	##Generate the simplified ts file## mapping={'STUDYID':['XYZ123'], 'TSPARMCD':['STSTDTC'], 'TSVAL':['YYYY-MM-DD'], 'TSVALNF':['']} with open ('C:/Simplified TS File/ts.xpt','wb') as f: xport.from_columns(mapping, f)

- **Note:** The Python Xport Module does not allow you to add data and variable labels to .xpt files.

Step 5 – After copying and pasting the code into the script editor, modify the code with your study parameters as follows:
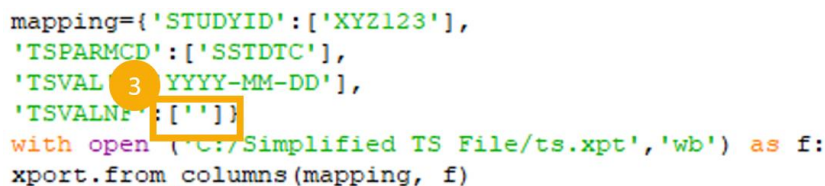
1. Next to STUDYID, replace 'XYZ123' with the applicable Study ID
2. Next to TSVAL, replace 'YYYY-MM-DD' with the applicable study start date

```
Python Code for Simplified TS.py - C:/Simplified TS File/Python Code for Sim
File  Edit  Format  Run  Options  Window  Help
##Import the xport module##

import xport

##Generate the simplified ts file##

mapping={'STUDYID':['XYZ123'],
'TSPARM':['SSTDTC'],
'TSVAL':['YYYY-MM-DD'],
'TSVALNF':['']}
with open ('C:/Simplified TS File/ts.xpt','wb') as f:
xport.from_columns(mapping, f)
```
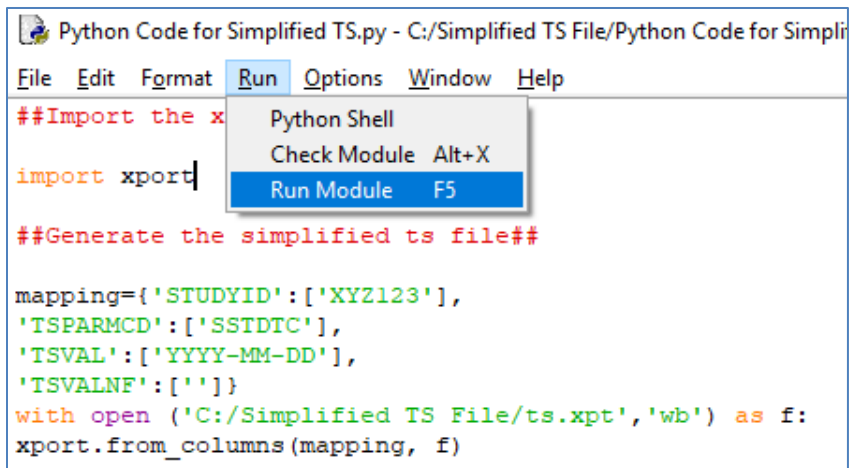
3. If no Study Start Date is available, delete 'YYYY-MM-DD', keeping the apostrophes , and next to 'TSVALNF', enter a valid Study Start Date Exception Code

```
mapping={'STUDYID':['XYZ123'],
'TSPARMCD':['SSTDTC'],
'TSVAL':['YYYY-MM-DD'],
'TSVALNF':['']}
with open ('C:/Simplified TS File/ts.xpt','wb') as f:
xport.from_columns(mapping, f)
```

Step 6 – Run the Python Script. A Python shell window will pop up and the TS.xpt file will be generated
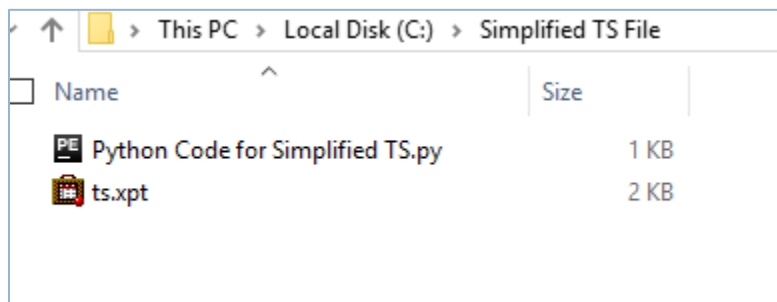
```
Python Code for Simplified TS.py - C:/Simplified TS File/Python Code for Simpli
File  Edit  Format  Run  Options  Window  Help
##Import the x     Python Shell
                   Check Module   Alt+X
import xport       Run Module     F5
##Generate the simplified ts file##

mapping={'STUDYID':['XYZ123'],
'TSPARMCD':['SSTDTC'],
'TSVAL':['YYYY-MM-DD'],
'TSVALNF':['']}
with open ('C:/Simplified TS File/ts.xpt','wb') as f:
xport.from_columns(mapping, f)
```

Step 7 – View the TS.xpt file in the folder created in Step 1, above.

```
↑    >  This PC  >  Local Disk (C:)  >  Simplified TS File

Name                                    Size

   Python Code for Simplified TS.py        1 KB
   ts.xpt                                  2 KB
```

3. VERIFY CREATED TS.XPT FILE
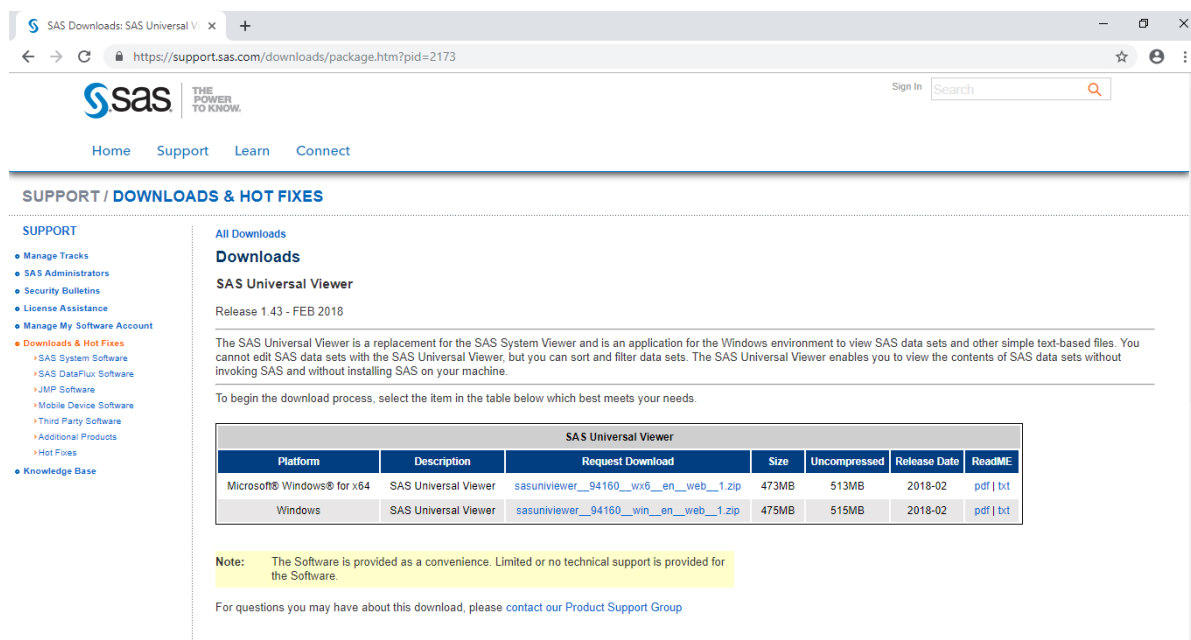
The reader can use any market available tools to review and verify the ts.xpt file. One example of such tools that's available to use is the SAS Universal Viewer. The instructions for installing and using SAS Universal Viewer are provided below.

a) Pre-Requisite: Install SAS Universal Viewer

The SAS Universal Viewer is installed on the reader's computer to open and view Simplified TS Files:

To install the SAS Universal Viewer, please refer to https://support.sas.com/downloads/package.htm?pid=2173 and follow the installation instructions.

Readers with an existing SAS user accounts can log in and download package through the link; new users will create an account first, then access to the link.
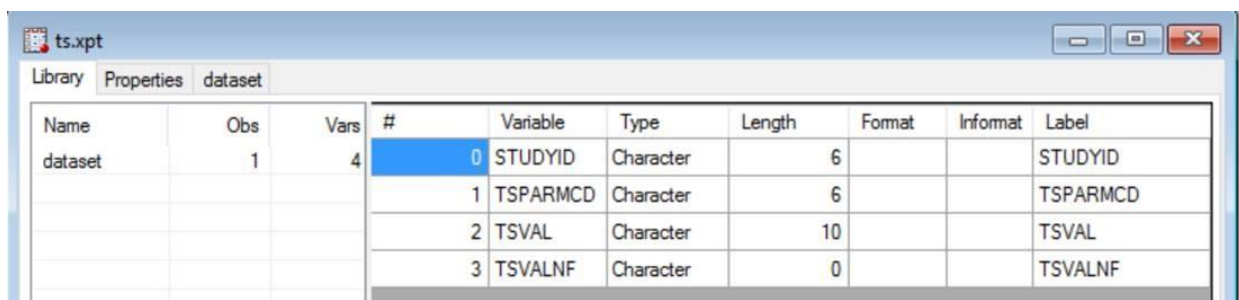

b) Open and Review Generated TS.xpt File

After creating the simplified ts.xpt file, please open the file in SAS Universal Viewer to make sure it is formatted correctly and includes the correct Study ID and Study Start Date.

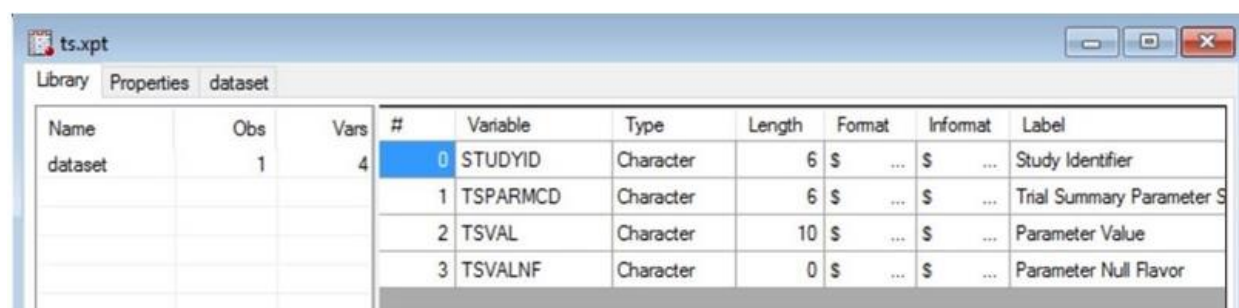Open the Simplified TS File in SAS Universal Viewer with the following steps:

- Open SAS Universal Viewer
- From the File menu select Open
- Enter the file path of the Simplified TS File in the Address field to open the file (C:/Simplified TS File in the sample code)

Figure 3: Example View of a Clinical Study
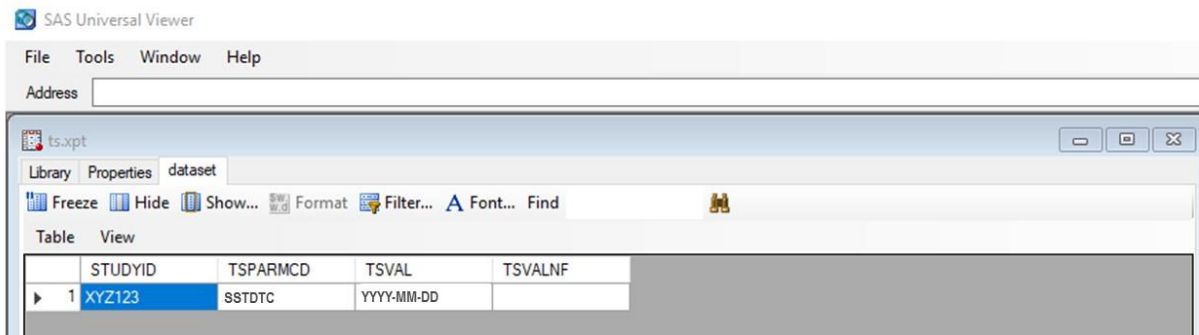
Properties for Simplified TS files can be viewed under the Properties tab in SAS Universal Viewer. Because the Python Xport Module does not have advanced properties capabilities, metadata such as variable labels cannot be assigned. The R packages include more advanced capabilities to edit XPT file properties. Figures 4 and 5 illustrate the differences between Simplified TS Files created in Python and R. In Python, the Variable Labels are assigned by default and are the same as the Variable Names. In R, the Variable Labels can be assigned and are labelled with the full description of the variables, as they would be labelled in a Full TS File that conforms to CDISC standards. The sample code for R includes the appropriate Variable Labels.

Figure 4: Example View of File Properties of Simplified TS File Created with Python

Figure 5: Example View of File Properties of Simplified TS File Created with R

4. APPENDIX: ADDITIONAL RESOURCES

Document	Link
Technical Rejection Criteria for Study Data	https://www.fda.gov/media/100743/download

Python Download & Installation Instructions	www.python.org/downloads
R Download & Installation Instructions	www.r-project.org
Xport Module Information	https://pypi.org/project/xport/
SAS Universal Viewer Download & Installation Instructions	https://support.sas.com/downloads/package.htm?pid=2173