

# **CREATING SIMPLIFIED TS.XPT FILES**

This Document is incorporated by reference into the following Guidance Document(s):

## **Study Data Technical Conformance Guide**

For questions regarding this technical specifications document, contact CDER at [cder-edata@fda.hhs.gov](mailto:cder-edata@fda.hhs.gov) or CBER at [cber.cdisc@fda.hhs.gov](mailto:cber.cdisc@fda.hhs.gov)

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)**

**November 2019**



**U.S. FOOD & DRUG**  
ADMINISTRATION

## **CREATING SIMPLIFIED TS.XPT FILES**

**November 2019**

Revision History		
Date	Version	Summary of Revisions
November 2019	1.0	Initial Version

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## BACKGROUND

This guide is intended to help sponsors create Simplified TS (ts.xpt) Files 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).

Please see the *Technical Rejection Criteria for Study Data*<sup>1</sup> and the *Study Data Technical Conformance Guide*<sup>2</sup> to determine if a Simplified TS will be required while submitting study information to FDA.

Simplified TS Files are SAS Transport files (.xpt) which can be created using free and open-source software, including R and Python. SAS Transport files are commonly used in CDISC standards; however, Simplified TS Files do not fully conform to CDISC standards.

**Option 1: Use R** – This section 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, such as Study ID and Study Start Date.

**Option 2: Use Python** – This section 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<sup>3</sup> to view the Simplified TS Files you create.

*Please Note* – This Guide provides examples and instructions only for Windows operating systems, some functions and steps may vary for users on other operating systems.

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1 Available at <https://www.fda.gov/industry/study-data-standards-resources/study-data-submission-cder-and-cber>

2 Available at <https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources>

3 SAS Universal Viewer is one of many applications to view SAS Transport, .xpt, files. FDA does not recommend the use of any software or applications. Users are free to choose the software of their choice. Learn more about the SAS Universal Viewer at <https://support.sas.com/downloads/package.htm?pid=2173>

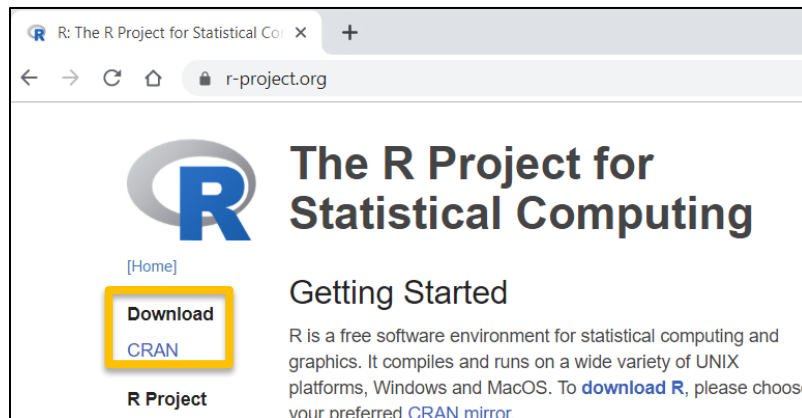
## CREATE SIMPLIFIED TS.XPT FILES

### a) Option 1: Use R

#### i) Pre-Requisite: Install R

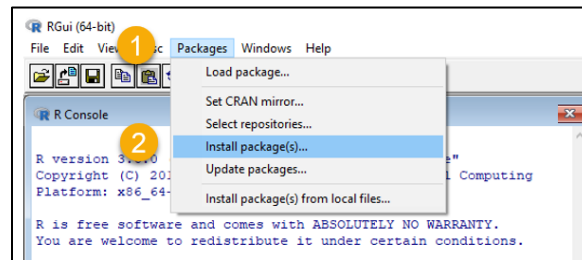
To install R, please refer to [www.r-project.org](http://www.r-project.org) and follow the installation instructions.<sup>4</sup>

*Please Note – This Guide does not provide detailed instructions on how to install R.*



Once you have installed R, open the R application and install R packages.

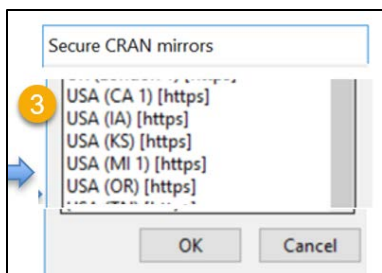
1. Select the “Packages” menu
2. Select “Install Package(s)”



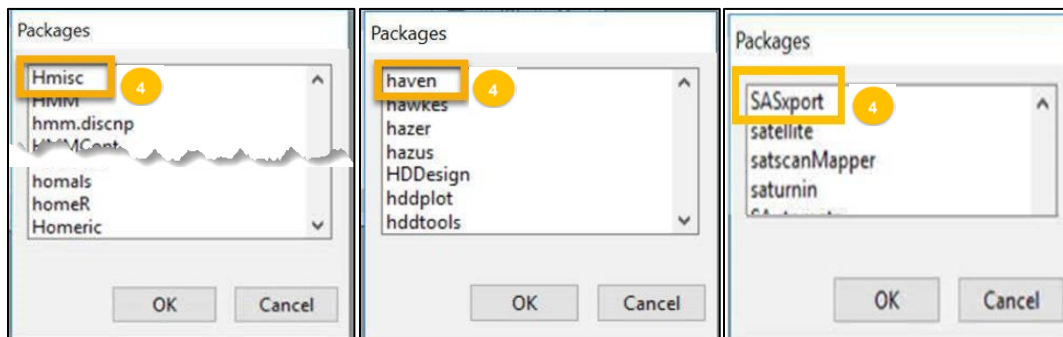
3. Select a CRAN Mirror.

*Please Note – You may select any CRAN mirror, but it is recommended that you select one close to your geographical proximity.*

<sup>4</sup> Learn more about R at <https://www.r-project.org/>.

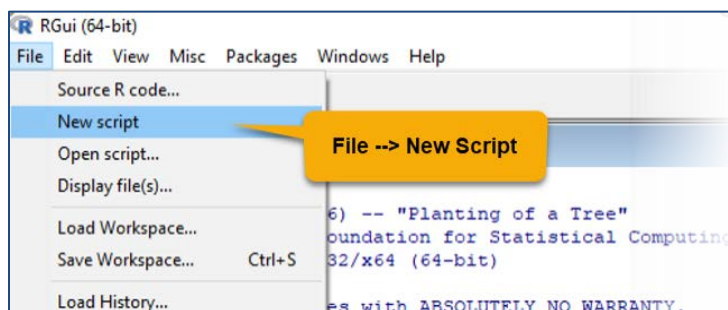


4. Install “Hmisc” and either “haven” or “SASxport.”



**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 or Table 2, depending on the type of study and which R package you are using:

Option A - Using the Haven Package or

Option B - Using the SASxport Package

**Table 1: Code for Creating ts.xpt Using R : Option A - Using the Haven Package**

R Package	Clinical Study	Non-clinical Study
<p><b>Option A:</b> Using the Haven Package</p>	<pre>####Load Packages#### library(haven) library(Hmisc)  data&lt;- data.frame(STUDYID="XYZ123",             TSPARMCD="SSTDTC",              TSVAL=strftime(as.Date("YYYY-MM-DD"), "%Y-%m-%d"),             TSVALNF="NA",             stringsAsFactors = FALSE)  ##add labels## label(data)&lt;-'Trial Summary' label(data[['STUDYID']])&lt;-'Study Identifier' label(data[['TSPARMCD']])&lt;-'Trial Summary Parameter Short Name' label(data[['TSVAL']])&lt;-'Parameter Value' label(data[['TSVALNF']])&lt;-'Parameter Null Flavor'  write_xpt(data, path="C:/Simplified TS File/ts.xpt", version=5)</pre>	<pre>####Load Packages#### library(haven) library(Hmisc)  data&lt;- data.frame(STUDYID="XYZ123",             TSPARMCD="STSTDTC",              TSVAL=strftime(as.Date("YYYY-MM-DD"), "%Y-%m-%d"),             TSVALNF="NA",             stringsAsFactors = FALSE)  ##add labels## label(data)&lt;-'Trial Summary' label(data[['STUDYID']])&lt;-'Study Identifier' label(data[['TSPARMCD']])&lt;-'Trial Summary Parameter Short Name' label(data[['TSVAL']])&lt;-'Parameter Value' label(data[['TSVALNF']])&lt;-'Parameter Null Flavor'  write_xpt(data, path="C:/Simplified TS File/ts.xpt", version=5)</pre>



**Table 2: Code for Creating ts.xpt Using R : Option B - Using the SASxport Package**

R Package	Clinical Study	Non-clinical Study
<p><b>Option B:</b> Using the SASxport Package</p>	<pre>##Load package## library(SASxport) library(Hmisc)  ##Create data file## abc&lt;-data.frame(STUDYID="XYZ123",                 TSPARMCD="SSTDTC",                  TSVAl=strftime(as.Date("YYYY-MM-DD"), "%Y-%m-%d"),                 TSVAlNF="NA",                 stringsAsFactors = FALSE)  ##Add labels##  label(abc) &lt;- 'Trial Summary' label(abc\$STUDYID)&lt;-'Study Identifier' label(abc\$TSPARMCD)&lt;-'Trial Summary Parameter Short Name' label(abc\$TSVAL)&lt;-'Parameter Value' label(abc\$TSVALNF)&lt;-'Parameter Null Flavor'  ##Write data into xpt format##  write.xport(abc, file="C:/Simplified TS File/ts.xpt")</pre>	<pre>##Load package## library(SASxport) library(Hmisc)  ##Create data file## abc&lt;-data.frame(STUDYID="XYZ123",                 TSPARMCD="STSTDTC",                  TSVAl=strftime(as.Date("YYYY-MM-DD"), "%Y-%m-%d"),                 TSVAlNF="NA",                 stringsAsFactors = FALSE)  ##Add labels##  label(abc) &lt;- 'Trial Summary' label(abc\$STUDYID)&lt;-'Study Identifier' label(abc\$TSPARMCD)&lt;-'Trial Summary Parameter Short Name' label(abc\$TSVAL)&lt;-'Parameter Value' label(abc\$TSVALNF)&lt;-'Parameter Null Flavor'  ##Write data into xpt format##  write.xport(abc, file="C:/Simplified TS File/ts.xpt")</pre>

**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 a Study Start Date is not available or applicable, delete “YYYY-MM-DD”, keeping the quotation marks and next to “TSVALNF”, enter “NA”

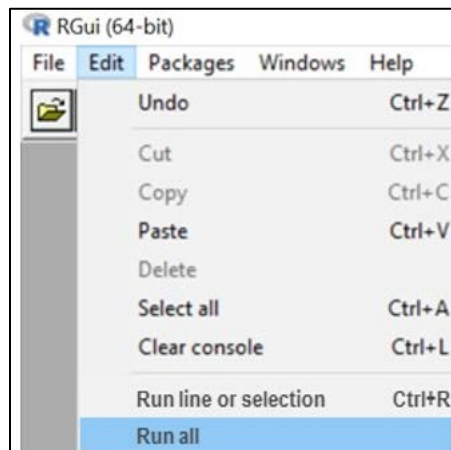
```

Untitled - R Editor
###Load Packages###
library(haven)
library(Hmisc)
data<-data.frame(STUDYID="XYZ123",
                 TSPARMCD="SSTDTC",
                 TSVAl=strftime(as.Date("YYYY-MM-DD"), "%Y-%m-%d"),
                 TSVAlNF="NA",
                 stringsAsFactors = FALSE)

##add 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'
    
```

Please 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 location you provided.



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 where you would like to save the file.

```

##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)
    
```

Please Note – When adding a new file path, be sure the slash marks are forwards (“/”). Backward slashes will result in an error when running the code.

**b) Option 2: Use Python**

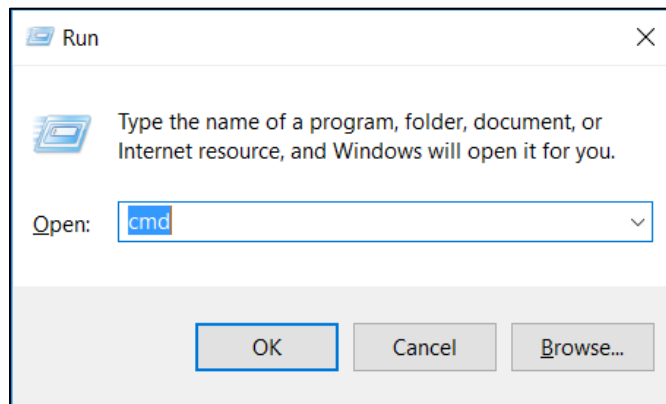
**i) Pre-Requisite: Install Python and IDLE**

To install Python and IDLE, please refer to [www.python.org/downloads](http://www.python.org/downloads) and follow installation instructions.<sup>5</sup>



*Please Note – IDLE is an integrated development environment for Python, which has been bundled with the default installation of Python.*

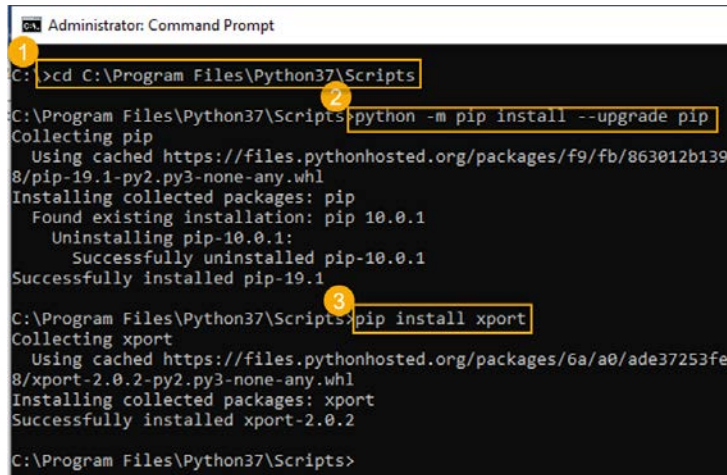
Launch Command Prompt in Windows (Windows Key+R) and type “cmd”



1. At the CMD.exe command line interface, type in the following command and press ENTER:  
`cd C:\Program Files\Python37\Scripts`  
*Please Note – This path may vary depending upon the directory where python was installed.*
2. Type in: `python -m pip install --upgrade pip` (to ensure pip is at the latest version).  
*Please Note – This step is optional.*

<sup>5</sup> Learn more about Python at <https://www.python.org/>.

3. Type in: pip install xport (to install the xport module)<sup>6</sup>

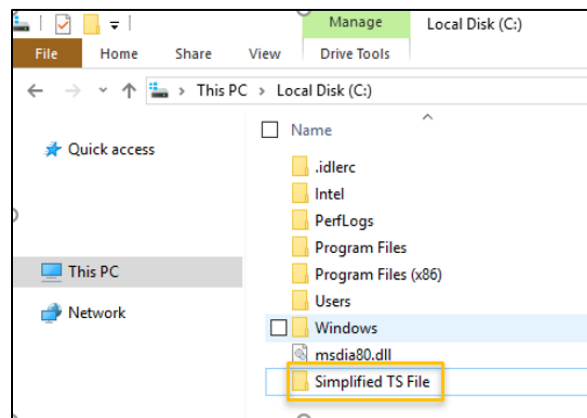


```
Administrator: Command Prompt
C:\Program Files\Python37\Scripts>cd C:\Program Files\Python37\Scripts
C:\Program Files\Python37\Scripts>python -m pip install --upgrade pip
Collecting pip
  Using cached https://files.pythonhosted.org/packages/f9/fb/863012b139
8/pip-19.1-py2.py3-none-any.whl
Installing collected packages: pip
  Found existing installation: pip 10.0.1
  Uninstalling pip-10.0.1:
    Successfully uninstalled pip-10.0.1
  Successfully installed pip-19.1
C:\Program Files\Python37\Scripts>pip install xport
Collecting xport
  Using cached https://files.pythonhosted.org/packages/6a/a0/ade37253fe
8/xport-2.0.2-py2.py3-none-any.whl
Installing collected packages: xport
  Successfully installed xport-2.0.2
C:\Program Files\Python37\Scripts>
```

## ii) Create Simplified ts.xpt Using Python

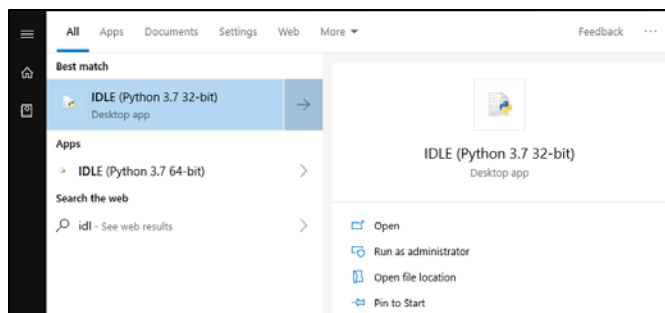
Create a Simplified TS File in Python with the following steps:

**Step 1** – Create a folder in C Drive or any file path, i.e. where the Simplified TS File will be saved and name it as e.g. “Simplified TS File.”



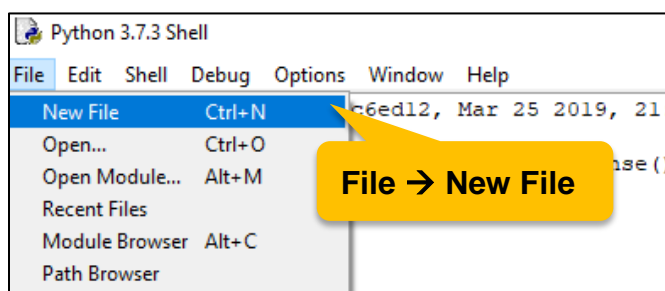
**Step 2** – Open the IDLE application.

<sup>6</sup> Learn more about the xport module at <https://pypi.org/project/xport/>.



Please Note – IDLE is an integrated development environment for Python, which has been bundled with the default installation of Python.

### Step 3 – Create New File



Step 4 – In Python Editor window copy and paste the applicable code from Table 3 and save the file with any file name, e.g. “Python Code for Simplified TS.”

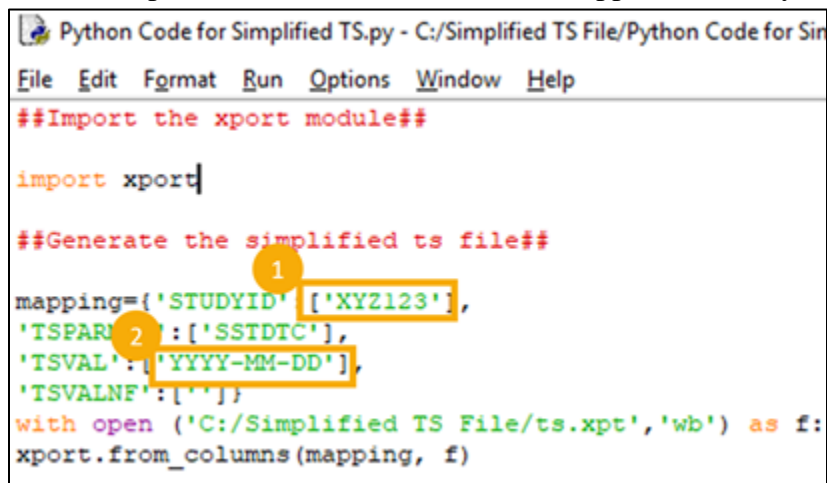
**Table 3: Code for Creating Simplified ts.xpt Using Python**

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

Please Note – The Python Xport Module does not allow you to add data and variable labels to .xpt files.

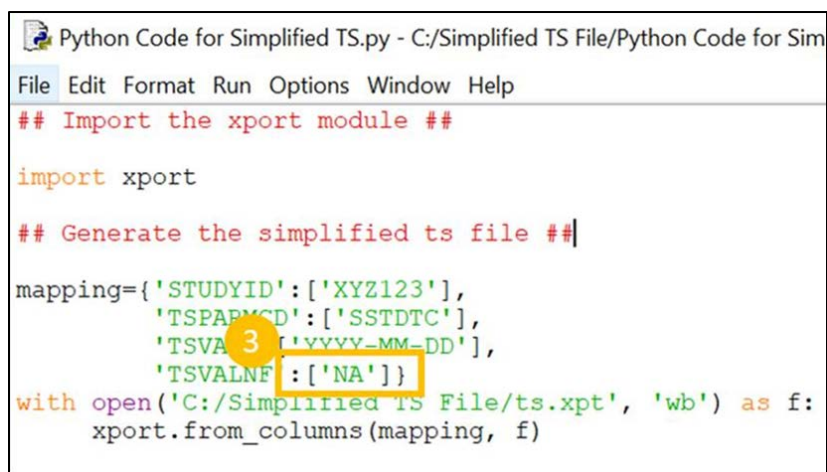
**Step 5** – After copying and pasting the code into the script editor, modify the code with your study parameters as follows:

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



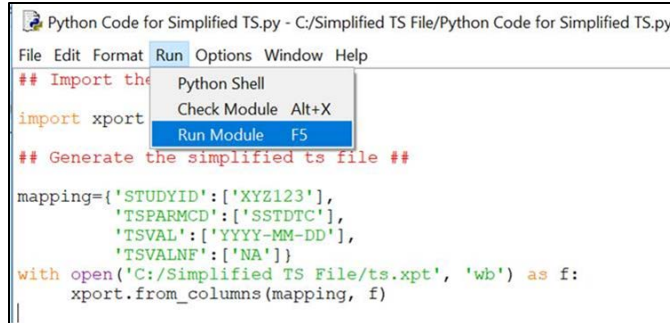
```
Python Code for Simplified TS.py - C:/Simplified TS File/Python Code for Sim
File Edit Format Run Options Window Help
##Import the xport module##
import xport
##Generate the simplified ts file##
mapping={'STUDYID': ['XYZ123'],
'TSPARMCD': ['SSTDTC'],
'TSVAL': ['YYYY-MM-DD'],
'TSVALNF': ['']}
with open ('C:/Simplified TS File/ts.xpt', 'wb') as f:
xport.from_columns(mapping, f)
```

3. If a Study Start Date is not available or applicable, delete ‘YYYY-MM-DD’, keeping the apostrophes, and next to ‘TSVALNF’, enter ‘NA’



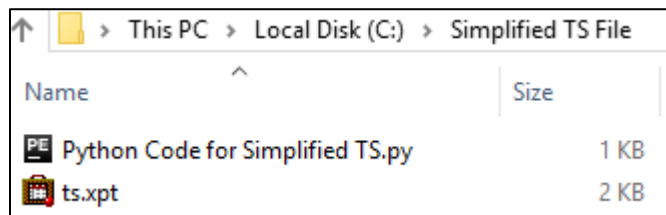
```
Python Code for Simplified TS.py - C:/Simplified TS File/Python Code for Sim
File Edit Format Run Options Window Help
## Import the xport module ##
import xport
## Generate the simplified ts file ##
mapping={'STUDYID': ['XYZ123'],
'TSPARMCD': ['SSTDTC'],
'TSVALNF': ['NA']}
with open ('C:/Simplified 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 Simplified ts.xpt file will be generated.



```
Python Code for Simplified TS.py - C:/Simplified TS File/Python Code for Simplified TS.py
File Edit Format Run Options Window Help
## Import the
import xport
## Generate the simplified ts file ##
mapping={'STUDYID':['XYZ123'],
         'TSPARMCD':['SSTDTC'],
         'TSVAL':['YYYY-MM-DD'],
         'TSVALNF':['NA']}
with open('C:/Simplified TS File/ts.xpt', 'wb') as f:
    xport.from_columns(mapping, f)
```

**Step 7** – Verify that the Simplified TS File in .xpt format is saved in the folder location you provided.





## VERIFY CREATED TS.XPT FILE

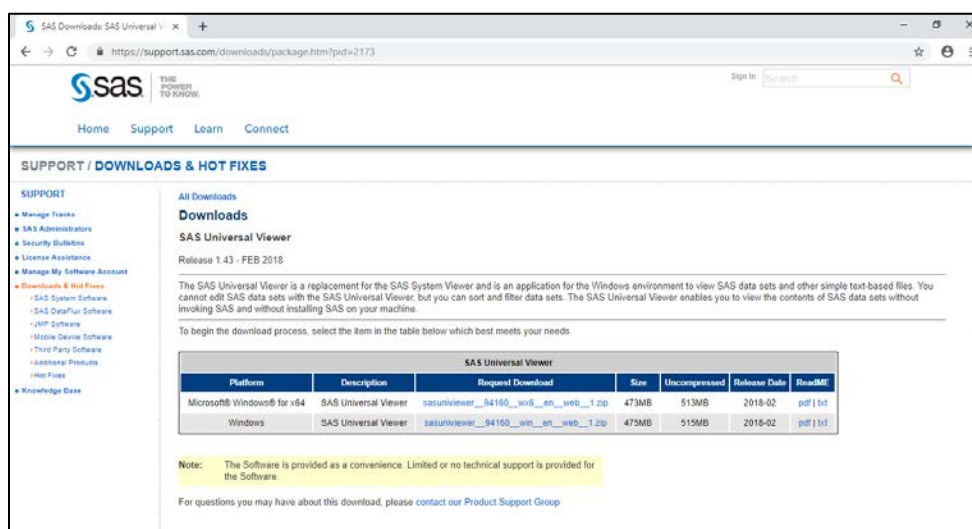
There are several available tools to review and verify the ts.xpt file. SAS Universal Viewer is one such tool. Instructions to install and use SAS Universal Viewer are provided below.

### 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 Simplified 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 information (e.g., 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 Simplified ts.xpt for a Clinical Study with a Study Start Date**

Table	View			
	STUDYID	TSPARMCD	TSVAL	TSVALNF
▶ 1	XYZ123	SSTDTC	YYYY-MM-DD	

**Figure 4: Example View of a Simplified ts.xpt for a Non-clinical Study with a Study Start Date**

Table	View			
	STUDYID	TSPARMCD	TSVAL	TSVALNF
▶ 1	XYZ123	STSTDTC	YYYY-MM-DD	

**Figure 5: Example View of a Simplified ts.xpt for a Clinical Study with No Study Start Date**

Table	View			
	STUDYID	TSPARMCD	TSVAL	TSVALNF
▶ 1	XYZ123	SSTDTC		NA

**Figure 6: Example View of a Simplified ts.xpt for Non-clinical Study when a Study Start Date is not Applicable**

Table	View			
	STUDYID	TSPARMCD	TSVAL	TSVALNF
▶ 1	XYZ123	STSTDTC		NA

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 7 and 8 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 7: Example View of File Properties of Simplified TS File Created with Python**

Name	Obs	Vars	#	Variable	Type	Length	Format	Informat	Label
dataset	1	4	0	STUDYID	Character	6			STUDYID
			1	TSPARMCD	Character	6			TSPARMCD
			2	TSVAL	Character	10			TSVAL
			3	TSVALNF	Character	0			TSVALNF

**Figure 8: Example View of File Properties of Simplified TS File Created with R**

Name	Obs	Vars	#	Variable	Type	Length	Format	Informat	Label
dataset	1	4	0	STUDYID	Character	6	\$ ...	\$ ...	Study Identifier
			1	TSPARMCD	Character	6	\$ ...	\$ ...	Trial Summary Parameter S
			2	TSVAL	Character	10	\$ ...	\$ ...	Parameter Value
			3	TSVALNF	Character	0	\$ ...	\$ ...	Parameter Null Flavor