

Table of Contents (TOC) – An Application of PowerShell®

Sumit Pratap Pradhan, Syneos Health®, Gurgaon, India

Navneet Agnihotri, Syneos Health®, Gurgaon, India

ABSTRACT

Trial Master File (TMF) is set up at the beginning of clinical trial. It is a collection of all essential documents pertaining to the trial. After each delivery (e.g. dry run), we are supposed to file documents like specification, qc plan, datasets, table, listing and figures on TMF. Uploading specification is easy as this is single file but uploading documents like datasets/tables requires to create a zip file and table of contents (TOC) because it is collection of multiple files. TOC is rtf file having listing of files included under Zip file. Manually creating TOC will require significant time. Since this is repetitive task, it can be automated to save the effort.

PowerShell can be used here. PowerShell is a cross-platform task automation solution made up of a command-line shell, a scripting language. With PowerShell, an GUI will be developed which will ask key information from user and based on input provided, shell scripting and SAS will be used for generating TOC.

INTRODUCTION

This tool creates a collection of zip files and a supporting table of contents (TOC) along with collection of individual files that can be directly uploaded to the TMF. Tool can create package in based upon the input information available. Below are 2 scenarios:

1) Study-status-tracker is created for the study - Tool will select files based on information available in tracker and will create package accordingly.

2) Study-status-tracker is not available - Manual effort will be needed before package creation.

Both scenarios are explained separately in this paper.

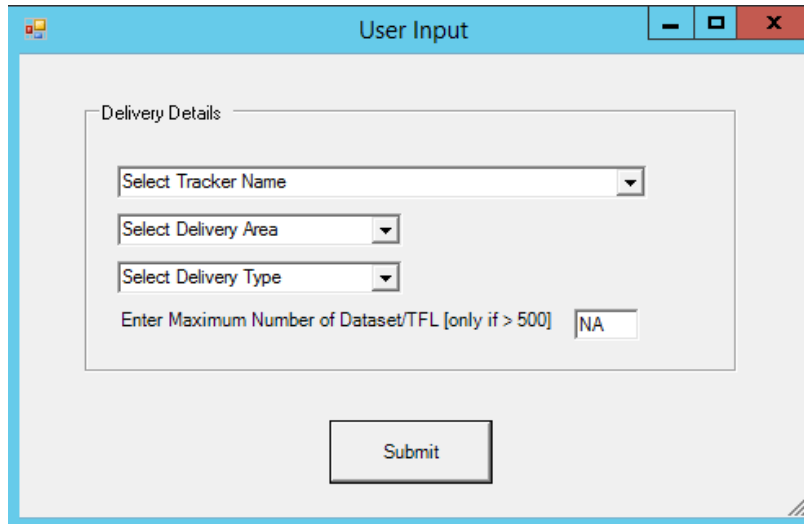
SCENARIO 1

Assumption in this scenario is - study status tracker is created for the study. Study status tracker is XLS file having information of items (SDTM datasets, ADaM Datasets, TFLs) to be developed for the study. Study status tracker should be updated accurately throughout the study cycle. An example of tracker is shown below. Following fields are mandatory

- Name of the output (example t-14-01-01)
- Delivery Date
- Program Name

Output	TFL Title	Category	Delivery Date	Program Name
t-14-01-01-01	Subject Enrollment and Disposition by Dose Level and Overall	Table	01-Nov-22	t-14-01-01-01.sas
t-14-01-02-01-01	Demographic and Baseline Characteristics by Dose Level and Overall (Enrolled Set)	Table	15-Nov-22	t-14-01-02-01-01.sas
t-14-01-02-01-02	Demographic and Baseline Characteristics by Dose Level and Overall (Per Protocol Set)	Table	15-Nov-22	t-14-01-02-01-01.sas
t-14-01-02-01-03	Demographic and Baseline Characteristics by Dose Level and Overall (Safety Set)	Table	15-Nov-22	t-14-01-02-01-01.sas

A PowerShell script is developed which will automate the process. User needs to run PowerShell script and following window will appear:

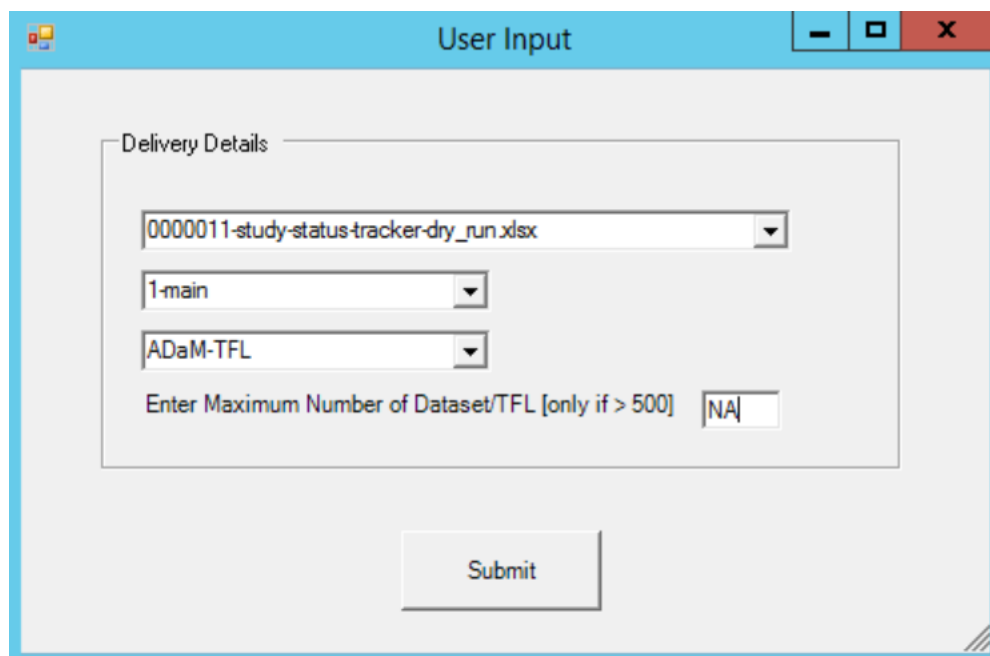


The screenshot shows a window titled "User Input" with a "Delivery Details" section. Inside this section, there are three drop-down menus labeled "Select Tracker Name", "Select Delivery Area", and "Select Delivery Type". Below these is a text input field labeled "Enter Maximum Number of Dataset/TFL [only if > 500]" with the value "NA" entered. A "Submit" button is located at the bottom of the window.

User needs to select the information from drop-down fields:

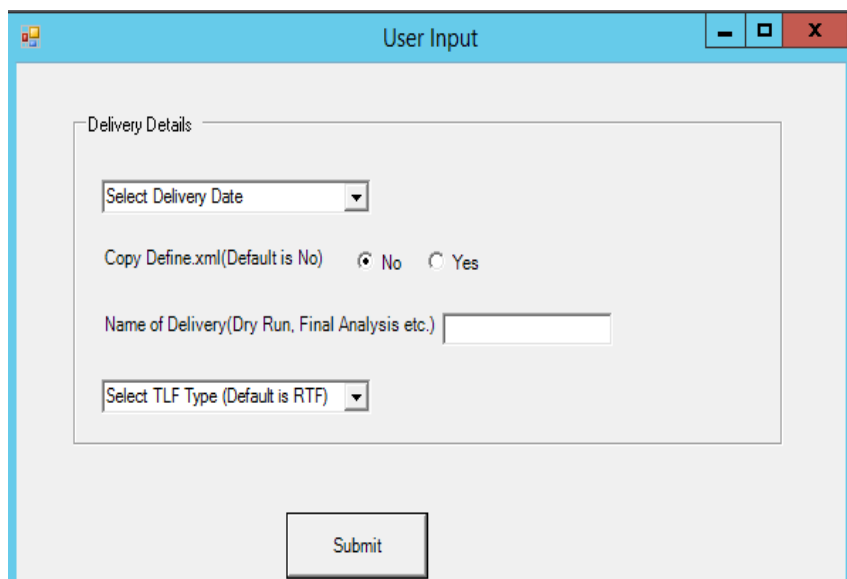
- 1st drop will display list of all study status trackers available to study. User needs to select appropriate tracker
- 2nd drop down will display list of all working area for study like drc, dsmb, main, topline, etc.
- 3rd drop down will display the component for which TMF package needs to be created. Example – ADaM, SDTM, ADaM-TFLs
 - Select ADaM if only ADaM datasets are being delivered
 - Select SDTM if only SDTM datasets are being delivered
 - Select ADaM-TFLs if ADaM datasets and TFLs are being delivered
- By default, tool considers that at maximum 500 items are available in any category (SDTM datasets, ADaM Datasets, TFLs). If any study has more than 500 items, approximate count needs to be mentioned in text box shown in 4th row. Example – if a study has 967 TFLs, user should enter 1000.

After User Selection, window will look like below screenshot.



The screenshot shows the same "User Input" window, but now the drop-down menus are populated. The "Select Tracker Name" menu shows "0000011-study-status-tracker-dry_run.xlsx". The "Select Delivery Area" menu shows "1-main". The "Select Delivery Type" menu shows "ADaM-TFL". The text input field for "Enter Maximum Number of Dataset/TFL [only if > 500]" still shows "NA". The "Submit" button remains at the bottom.

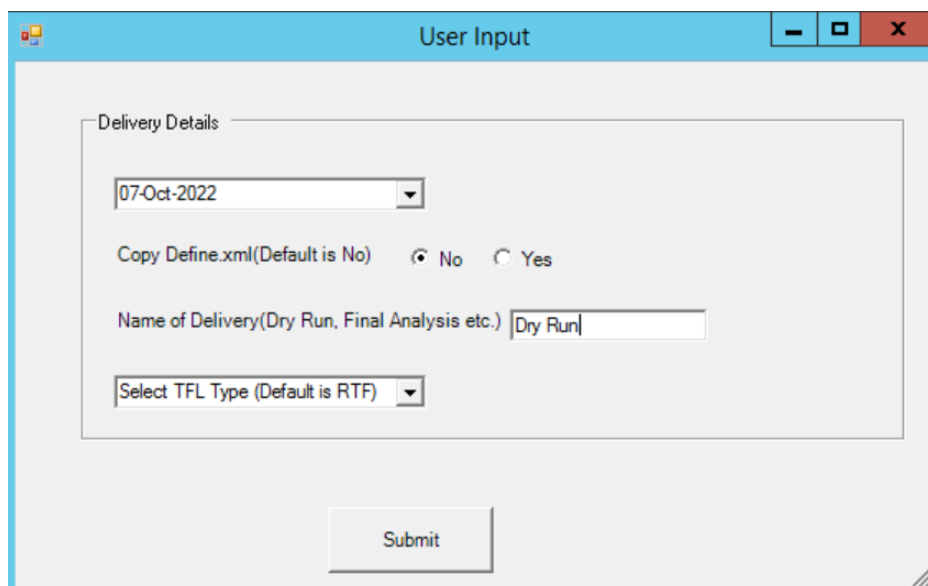
Next, clicking on Submit button will display next window which will look like below screenshot.



User needs to select/provide the following information:

- 1st drop will display list of all delivery dates available to tracker. User needs to select appropriate delivery date
- User may select Yes from 2nd row if Define XML is ready. By default, it will be No
- Name of delivery should be provided in 3rd row using text box
- TFL type (RTF, PDF) can be selected by user from 4th row using drop down field. By default, tool will select RTF files
 - This should be noted that tool will not create any file (RTF or PDF), files should be present at output location
 - 4th row is not applicable for components - SDTM datasets and ADaM datasets. It will not be displayed for if user selects SDTM or ADaM component

After User Selection, window will look like below screenshot.



Once user clicks on submit button, tool will start copying files based on input provided by user (options selected by user using window mentioned above). After copying, tool will create Zip and corresponding TOC files that can be uploaded to TMF. Final created package will look like below screenshot.

Name	Date modified	Type	Size
0000011_Dry_Run_adam_spec	10/7/2022 4:28 PM	File folder	
0000011_Dry_Run_tfl_metadata	10/7/2022 4:28 PM	File folder	
0000011_Dry_Run_ADaM_Datasets_2022-10-07_Dry_Run	10/7/2022 4:30 PM	Compressed (zipp...	6 KB
0000011_Dry_Run_ADaM_Datasets_2022-10-07_Dry_Run_TOC	10/7/2022 4:29 PM	Rich Text Format	4 KB
0000011_Dry_Run_ADaM_Programs_2022-10-07_Dry_Run	10/7/2022 4:30 PM	Compressed (zipp...	103 KB
0000011_Dry_Run_ADaM_Programs_2022-10-07_Dry_Run_TOC	10/7/2022 4:29 PM	Rich Text Format	24 KB
0000011_Dry_Run_TFL_Outputs_2022-10-07_Dry_Run	10/7/2022 4:30 PM	Compressed (zipp...	6 KB
0000011_Dry_Run_TFL_Outputs_2022-10-07_Dry_Run_TOC	10/7/2022 4:29 PM	Rich Text Format	5 KB
0000011_Dry_Run_TFL_Programs_2022-10-07_Dry_Run	10/7/2022 4:30 PM	Compressed (zipp...	103 KB
0000011_Dry_Run_TFL_Programs_2022-10-07_Dry_Run_TOC	10/7/2022 4:29 PM	Rich Text Format	24 KB

Few items should be filed individually like SDTM/ADaM specification, tfl-metadata etc. These items will be copied to specific folder and zip will not be created for these items (see first 2 rows in above screenshot).

SCENARIO 2

Consider the following circumstances.

- Study status tracker is not present for the study
- Study status tracker is created but it is not updated for items included in study

tool will not be able to collect information using GUI from user as shown in [Scenario 1](#). In this situation, following steps should be followed:

- User needs to copy files manually to specific location where TMF package needs to be created.
- User needs to arrange files in separate folders depending upon the type of file. Below screenshot shows example.

Name
0000011_Dry_Run_adam_spec
0000011_Dry_Run_tfl_metadata
0000011_Dry_Run_ADaM_Programs_2022-10-07_Dry_Run
0000011_Dry_Run_TFL_Programs_2022-10-07_Dry_Run
0000011_Dry_Run_ADaM_Datasets_2022-10-07_Dry_Run
0000011_Dry_Run_TFL_Outputs_2022-10-07_Dry_Run

- PowerShell script mentioned in [Scenario 1](#) is customized to work in [Scenario 2](#). User needs to run the customized script which will ask for location of TMF package to be created.
- When user runs script, following window will be shown.

Dashboard

User Input

Enter Location of TMF Package.
Enter in format D:\projects\sponsor\0009191\biostat\1-main

Submit

- User needs to enter location in textbox like below screenshot

Dashboard

User Input

Enter Location of TMF Package.
Enter in format D:\projects\sponsor\0009191\biostat\1-main

D:\projects\sponsor\0009191\biostat\1-main

Submit

- Once user provides location of TMF package and clicks on submit button, Package will be created like below screenshot

Name	Date modified	Type	Size
0000011_Dry_Run_adam_spec	10/7/2022 4:28 PM	File folder	
0000011_Dry_Run_tfl_metadata	10/7/2022 4:28 PM	File folder	
0000011_Dry_Run_ADaM_Datasets_2022-10-07_Dry_Run	10/7/2022 4:30 PM	Compressed (zipp...	6 KB
0000011_Dry_Run_ADaM_Datasets_2022-10-07_Dry_Run_TOC	10/7/2022 4:29 PM	Rich Text Format	4 KB
0000011_Dry_Run_ADaM_Programs_2022-10-07_Dry_Run	10/7/2022 4:30 PM	Compressed (zipp...	103 KB
0000011_Dry_Run_ADaM_Programs_2022-10-07_Dry_Run_TOC	10/7/2022 4:29 PM	Rich Text Format	24 KB
0000011_Dry_Run_TFL_Outputs_2022-10-07_Dry_Run	10/7/2022 4:30 PM	Compressed (zipp...	6 KB
0000011_Dry_Run_TFL_Outputs_2022-10-07_Dry_Run_TOC	10/7/2022 4:29 PM	Rich Text Format	5 KB
0000011_Dry_Run_TFL_Programs_2022-10-07_Dry_Run	10/7/2022 4:30 PM	Compressed (zipp...	103 KB
0000011_Dry_Run_TFL_Programs_2022-10-07_Dry_Run_TOC	10/7/2022 4:29 PM	Rich Text Format	24 KB

Few items should be filed individually like SDTM/ADaM specification, tfl-metadata etc. Zip file will not be created for these items (see first 2 rows in above screenshot).

SCRIPTING CONSIDERATION USING POWERSHELL

In this section few scenarios and references have been mentioned which details how PowerShell can be used to automate the process.

- Simple forms can be designed to take user input.
https://learn.microsoft.com/en-us/powershell/scripting/samples/creating-a-custom-input-box?view=powershell-7.2&WT.mc_id=email
- Conditional statement can be used to run specific code meeting specific criteria.
<https://learn.microsoft.com/en-us/powershell/scripting/learn/deep-dives/everything-about-if?view=powershell-7.2>
- Looping statement can be used to run specific code multiple times. Example – Looping can be used to add multiple items to drop down field.
https://learn.microsoft.com/en-us/powershell/module/microsoft.powershell.core/about/about_for?view=powershell-7.2

- Commands in PowerShell is known as cmdlets. Cmdlets can help to write scripts smoothly.
Example – Get-Item cmdlet can be used to get the item at the specified location. Below code will provide all files with extension .xlsx or .xlsm from specified location. Result of cmdlet will be stored in the variable file_list which can be used further in script.
\$file_list = (Get-Item "C:\projects\sponsor\1234\tracking*.*)" -Include "*.xlsx", "*.xlsm").name
<https://learn.microsoft.com/en-us/powershell/module/microsoft.powershell.management/?view=powershell-7.2>
- Functions are available in PowerShell which can be utilized to make the script more organized.
<https://learn.microsoft.com/en-us/powershell/scripting/learn/ps101/09-functions?view=powershell-7.2>

CONCLUSION

Tool is developed to reduce manual effort, minimize unnecessary time to perform repetitive task. Tool will ensure consistency and accuracy across studies. Since PowerShell is open source and pre-installed on Citrix environment (e.g. Windows Server 2012 R2), it requires no overhead for IT team to install any software. It is recommended to read PowerShell documentation mentioned in references section for detailed information.

REFERENCES

PowerShell Documentation

<https://docs.microsoft.com/en-us/powershell/>

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the authors at:

Sumit Pratap Pradhan
Syneos Health, Manager, Statistical Programming
DLF Downtown, DLF City Phase 3 Road, Sector 25A, Gurgaon - 122002, Haryana, India
E-mail: sumit.pradhan@syneoshealth.com
LinkedIn: <https://www.linkedin.com/in/sumit-pradhan-71133345/>

Navneet Agnihotri
Syneos Health, Principal Statistical Programmer
DLF Downtown, DLF City Phase 3 Road, Sector 25A, Gurgaon - 122002, Haryana, India
E-mail: navneet.agnihotri@syneoshealth.com
LinkedIn: <https://www.linkedin.com/in/navneet-agnihotri-78540553/>

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