

AD09

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

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Sumit Pratap Pradhan
Manager, Statistical
Programming

Sumit Pratap Pradhan, Advanced SAS certified, is working in Life Sciences domain and using SAS language for more than 10.5 years. Currently, He is associated with Syneos Health® for more than 6 years and working in the capacity of Manager, Statistical Programming. Prior to Syneos Health, he was a part of Tata Consultancy Services for 4.5 years. He has worked on Client Specific standard as well as CDISC standards (SDTM and ADaM). He likes to play computer games in free time.



Navneet Agnihotri
Principal Statistical
Programmer

Navneet is a seasoned professional in the space of Clinical and Life Sciences domain with a rich experience of 9.5 years in IT and CRO industry. Currently, he is associated with Syneos Health® for more than 5 years and working in the capacity of Principal Statistical Programmer wherein he is involved in end-to-end transformation and generation of CDISC compliant SDTM and ADaM packages for submission to reviewing authorities. Previous to Syneos Health, he was a part of Tata Consultancy Services for 4.5 years. He is a fun-loving guy who loves to travel and interact/socialize with people of all ages and areas.

AGENDA

- 01 Introduction
- 02 Background
- 03 Usage Scenario 1
- 04 Usage Scenario 2
- 05 Scripting overview
- 06 Conclusion
- 07 Q&A

Introduction

- TMF - collection of all essential documents
- Uploading specification vs documents like datasets/tables
- Zip file and table of contents (TOC)
- TOC - rtf file having listing of files included under Zip
- Automation – PowerShell and SAS

Background

- Package will be created based upon the input information available
- Study-status-tracker is created for the study - Tool will select files based on information available in tracker and will create package accordingly
- Study-status-tracker is not available - Manual effort will be needed before package creation

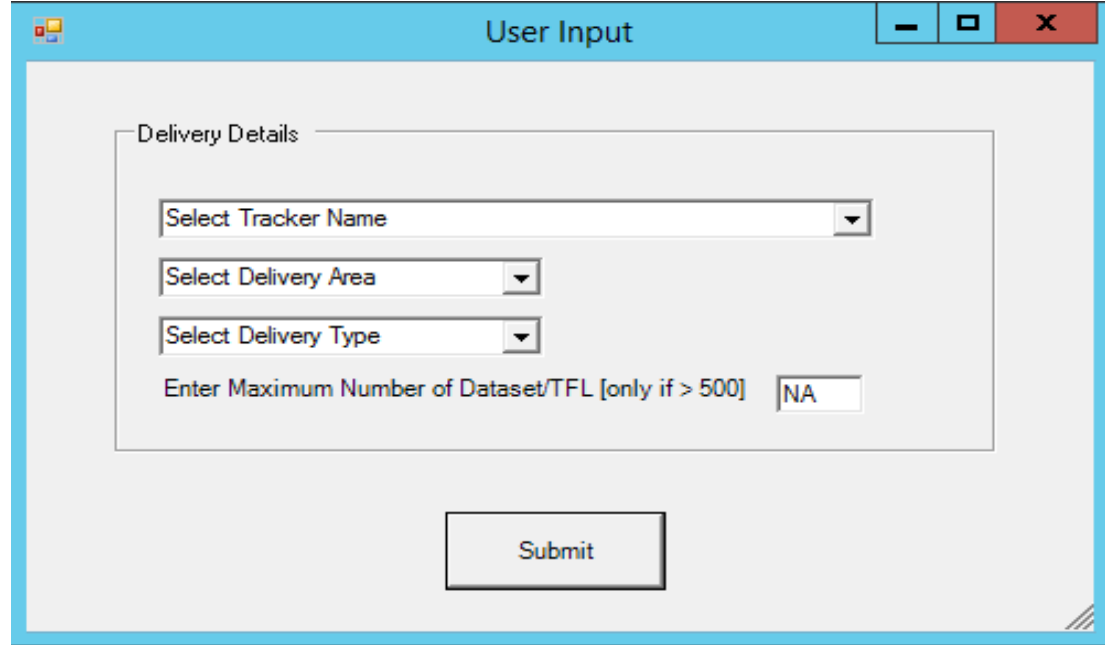
Scenario 1

- Study status tracker is created for the study

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

Scenario 1

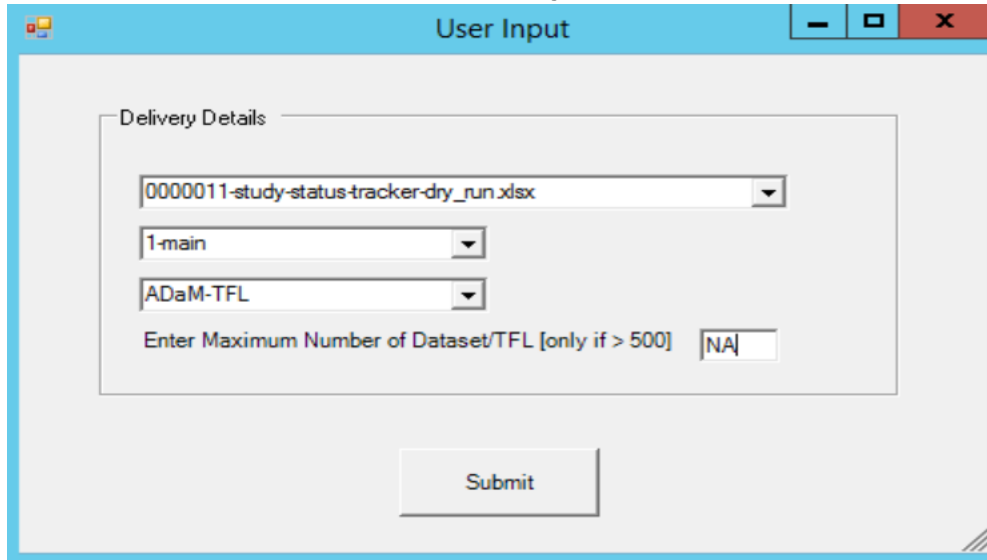
- PowerShell script
- User Input



The screenshot shows a Windows-style dialog box titled "User Input". Inside the dialog, there is a section titled "Delivery Details" which contains four input fields: three dropdown menus labeled "Select Tracker Name", "Select Delivery Area", and "Select Delivery Type", and 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 center of the dialog.

Scenario 1

- Options selected by user



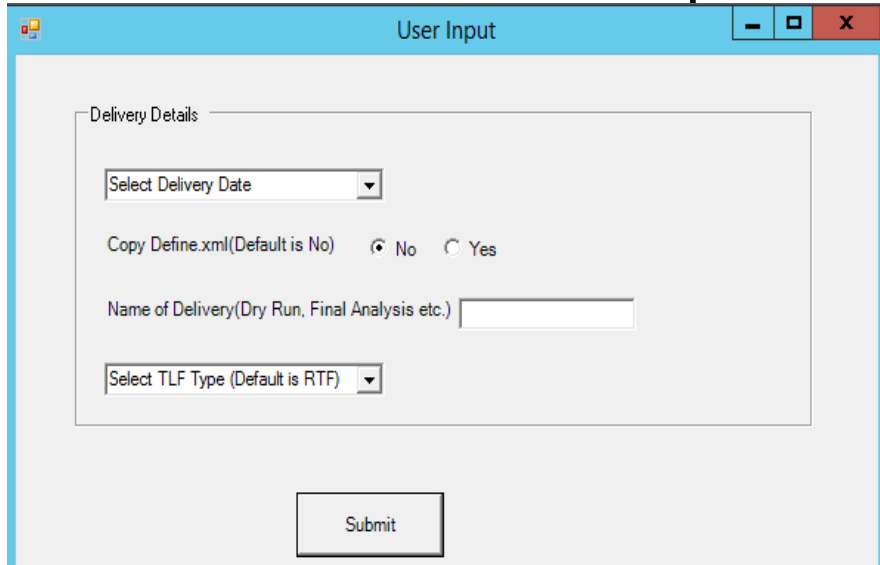
The screenshot shows a 'User Input' window with a 'Delivery Details' section. The selected options are:

- File: 0000011-study-status-tracker-dry_run.xlsx
- Study: 1-main
- Dataset: ADaM-TFL
- Enter Maximum Number of Dataset/TFL [only if > 500]: NA

A 'Submit' button is located at the bottom of the form.

Scenario 1

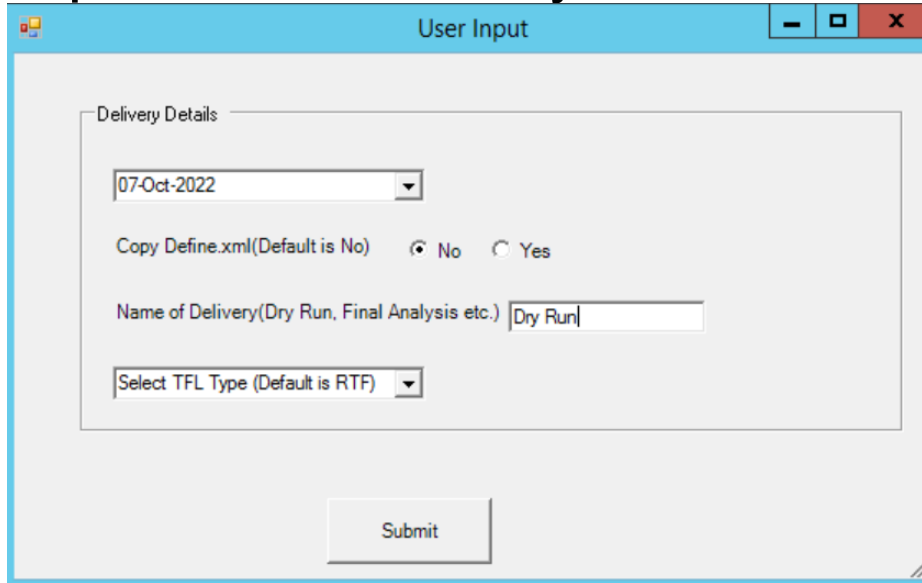
- Next window for user input



The screenshot shows a software window titled "User Input" with a standard Windows-style title bar (blue with minimize, maximize, and close buttons). The main content area is light gray and contains a section titled "Delivery Details" enclosed in a thin black border. Inside this section, there are four input fields: a dropdown menu labeled "Select Delivery Date", a radio button group for "Copy Define.xml(Default is No)" with "No" selected, a text input field for "Name of Delivery(Dry Run, Final Analysis etc.)", and another dropdown menu labeled "Select TLF Type (Default is RTF)". Below the "Delivery Details" section, centered at the bottom of the window, is a "Submit" button.

Scenario 1

- Options selected by user



The screenshot shows a 'User Input' dialog box with a light blue title bar and standard Windows window controls. Inside the dialog, there is a section titled 'Delivery Details' which contains four input fields: a date dropdown menu set to '07-Oct-2022', a radio button group for 'Copy Define.xml(Default is No)' with 'No' selected, a text input field for 'Name of Delivery(Dry Run, Final Analysis etc.)' containing 'Dry Run', and a dropdown menu for 'Select TFL Type (Default is RTF)'. A 'Submit' button is located at the bottom center of the dialog.

Scenario 1

- Package creation
 - Individual files like SDTM/ADaM specification, tfl-metadata
 - Zip file and corresponding TOC

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

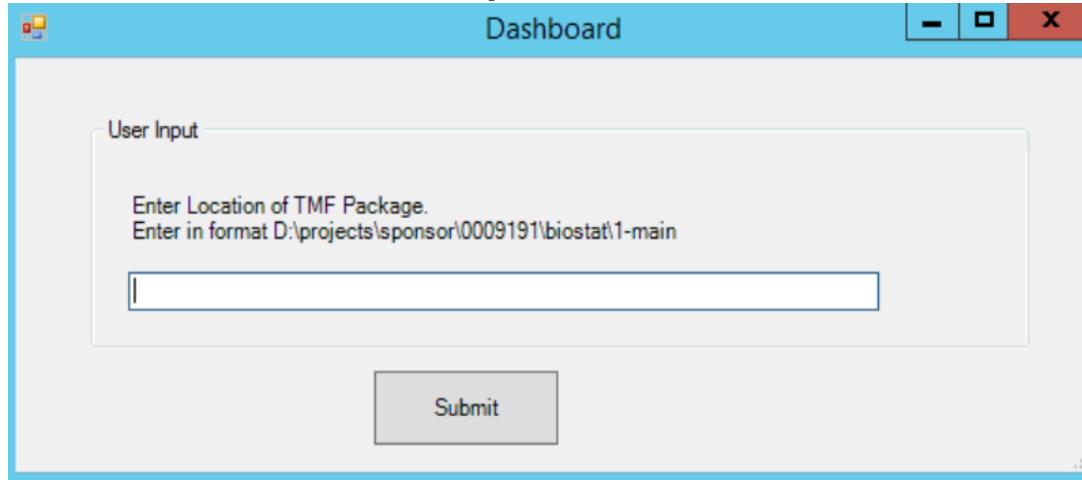
Scenario 2

- Study status tracker is not present
 - Not created
 - Not updated correctly
- Manual effort

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

Scenario 2

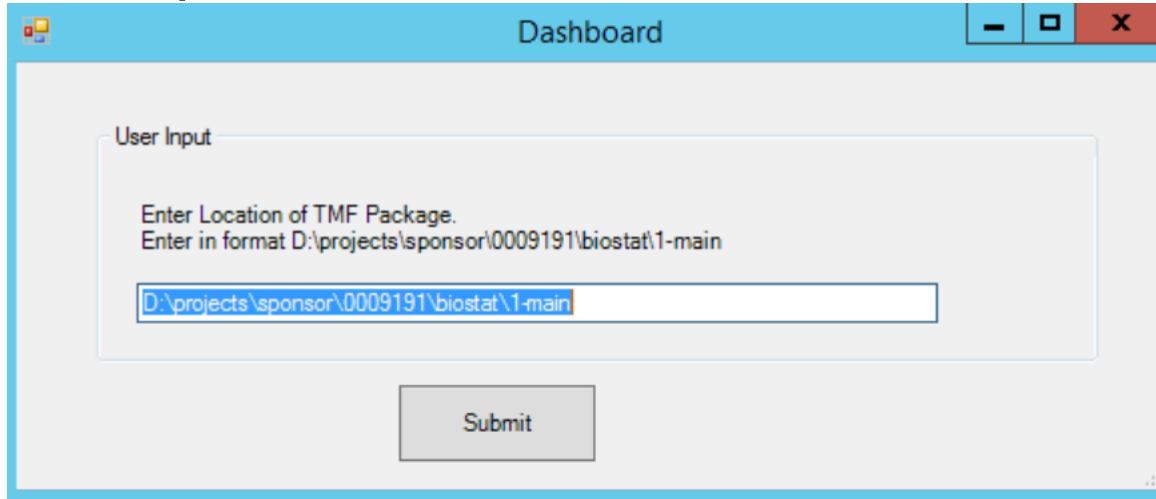
- Customized Script



The screenshot shows a web browser window with a blue title bar labeled 'Dashboard'. Inside the window, there is a 'User Input' section with a light gray background. This section contains the text 'Enter Location of TMF Package. Enter in format D:\projects\sponsor\0009191\biostat\1-main' and a text input field. Below the input field is a 'Submit' button.

Scenario 2

- User provides location



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

Scenario 2

- Package creation
 - Individual files like SDTM/ADaM specification, tfl-metadata
 - Zip file and corresponding TOC

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

Scripting overview

- 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>

Scripting overview

- 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.

<https://learn.microsoft.com/en-us/powershell/module/microsoft.powershell.management/?view=powershell-7.2>

Scripting overview

- 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

- Reduce manual effort and saves time
- Consistency and accuracy
- Open source and pre-installed
- No overhead for IT team

Q&A

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