

Dynamic Program Tracker

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ABSTRACT

A program tracking document for statistical programming in clinical trial is an essential document which gives us the progress report of the project. Maintaining this document is one of the prime responsibilities of a statistical programmer. By making the tracking document dynamic, we can check the development and validation status of programs which will in turn save time in assessing the status of the study with respect to statistical programming deliverables. A document which can dynamically track the process and alert the user of any process deviations can prove very helpful in statistical programming for clinical trial projects. Dynamic Program Tracker also greatly reduces the time and effort required to check if all programs are following the Program Development Life Cycle, as well as check for any issues with programs.

This paper will describe the design, features and comprehensive checks done by Dynamic Program Tracker. The code for Dynamic Program Tracker is developed in Microsoft VBA (Visual Basic for Applications) which is available within all Microsoft Office products - with no additional costs for new software. The purpose of this tracker is to check compliance and serve as a project management tool.

INTRODUCTION

Clinical trial statistical programming projects involve several programs which are required to create analysis datasets (ADaMs), tables, figures and listings (TFL). It is responsibility of study programmers to ensure that development and validation of such programs are following standard operating procedures (SOPs). Program tracking is an essential component to ensure compliance with SOPs. Automating program development and validation status tracking helps study programmers to manage program tracking in an efficient manner.

Dynamic Program Tracker (DPT) is an automated tool developed in the Biostatistics and Research Decision Sciences (BARDS) organization at Merck which tracks development and validation status along with checking some critical validation outputs like a PROC COMPARE report. This tool is developed using Microsoft® Excel VBA. Since Excel is the most commonly used tool for maintaining and tracking programming status, it is logical to develop an Excel VBA macro which can track programming status and ensure that programming project is compliant with SOPs. DPT requires Excel workbook with three sheets: Plan and Track, Dashboard and Issue Codes. The Plan and Track sheet contains list of programs related to analysis datasets and TFLs used in a particular study where programmers can populate the programming status. It also contains developer and validator programmer information assigned to each programs. The Dashboard sheet has control buttons to run VBA macros and provide metrics for project status. The Issue Codes sheet has the list of issue codes and decodes which can be referred by study programmers.

Dynamic Program Tracker mainly focuses on the items below:

- Identify study area
- Check developer programs and outputs
- Check validation programs and outputs (if applicable)
- Check if programs are run in order
- Check program header for version date, revision date and compare with program file date-time stamp
- Check PROC COMPARE report (if applicable)

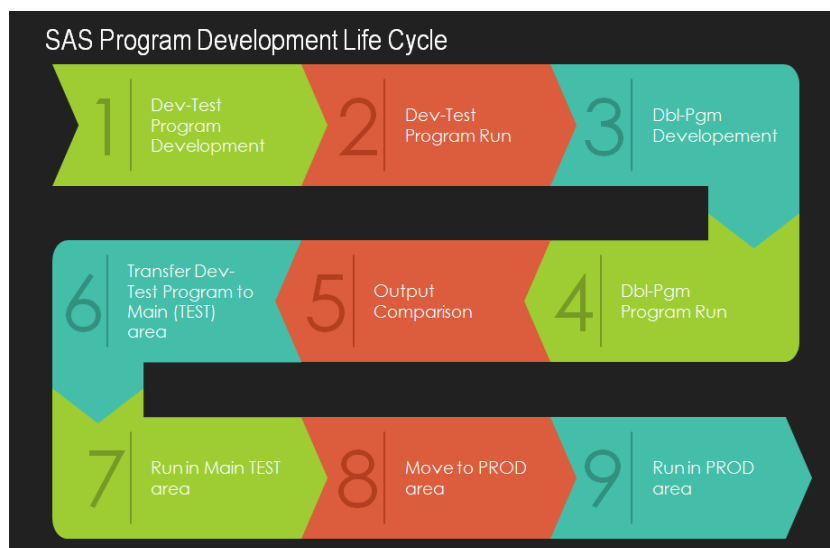


Figure2 – Program run sequence

Examples

Case 1:

Name	DEV-TEST	Date modified	Name	DBL-PGM	Date modified
adsl.log		10/9/2017 4:17 PM	adsl.sas7bdat		10/9/2017 3:33 PM
adsl.lst		10/9/2017 4:17 PM	logchecker_val0adsl.html		10/9/2017 3:33 PM
adsl.sas7bdat		10/9/2017 4:17 PM	val0adsl.log		10/9/2017 3:33 PM
			val0adsl.lst		10/9/2017 3:33 PM

Case 2:

Name	PGMSETUP	Date modified	Name	DEV-TEST	Date modified
adae.sas		10/9/2017 9:45 AM	adae.sas		9/28/2017 9:54 PM
adcm.sas		9/30/2017 3:06 PM			
addili.sas		9/29/2017 2:06 PM			

Case 3:

Name	PGMSETUP	Date modified	Name	DEV-TEST	Date modified
adplda.sas		9/21/2017 1:17 PM	adplda.sas		10/5/2017 2:27 PM
adpm.sas		8/27/2017 10:26 PM	startup-unix.sas		10/9/2017 11:25 PM
adpro.sas		10/6/2017 10:41 AM			

Figure 3 – Examples of discrepancies detected by dynamic program tracker

Dynamic program tracker does some comprehensive checks with respect to ADaM programs and TFL macros. It checks whether the SAS® log file date-time stamp is after the respective program file date-time stamp, which ensures that program is ran after modification. If a study uses standard macros, then it checks and compares file date-time stamp of standard macros in BARDS global standards area. If there is any inconsistency identified then user is notified.

CHECK PROGRAM HEADER

Program header is needed for every program to reflect good programming practices before user finalizes his/her program, which in turn gives vital information about program development, revision history dates, logic explanation, program flow etc. Often times while developing or updating a program, version date and revision history does not reflect the program updates. DPT has the capacity to read Merck standard program header version date and revision history date. The date read in program header is then compared with actual program file date-time stamp. If there is any discrepancy the user is notified.

CHECK PROC COMPARE REPORT

PROC COMPARE is a very useful SAS® procedure which is used to compare two datasets. This procedure is used by validator for double programming QC technique. The report generated by PROC COMPARE is stored and reviewed as validation evidence. DPT checks if report is available (if applicable) and reads it. If compared datasets are not matching then it notifies the user. This feature is very helpful for programming lead/manager to ensure that developer and validator are matching on their independent outputs.

COMPILE IDENTIFIED ISSUES

Dynamic program tracker performs detailed comprehensive checks. Any issues identified with program and outputs are compiled together in a column in the “Plan and Track” sheet. If any issues are identified then the DPT automatically populates identified issues in the respective row of each program listed in the “Plan and Track” sheet.

DASHBOARD WITH METRICS AND PROJECT STATUS GRAPHS

Dynamic program tracker has a dashboard which gives information on overall project status and metrics. A pie chart of completion status gives an overview of the project. Specific programming tasks like ADaM development/validation, TFL macro development/validation is shown by bar chart. A separate graph is used to display number of programs with and without issue with respect to developer and validator. More information regarding these graphs can be seen in figure 4.

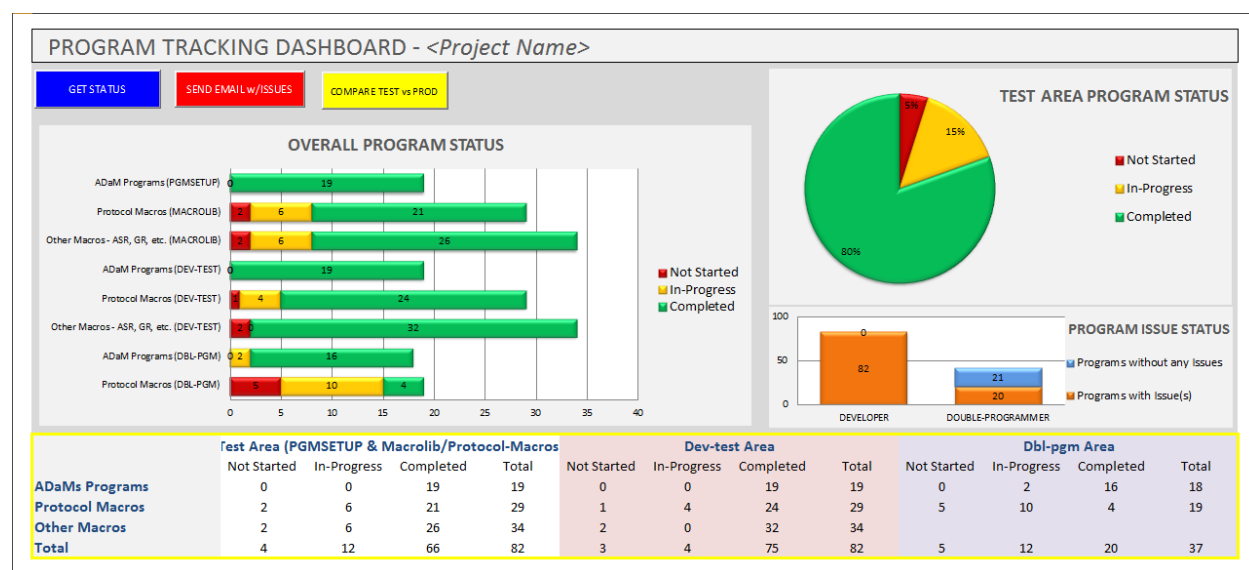


Figure 4 – Overall status graphs from dashboard

The Dynamic program tracker is also used as a project management tool. It provides distribution of programs with respect to programmers and also a graph with their weighted scores. Weighted score is calculated based on the complexity or the validation category of programs assigned to particular programmers. Example of project management graphs can be seen in figure 5.

The dashboard serves a very important purpose for tracking and displaying all the information via graphs and tables.

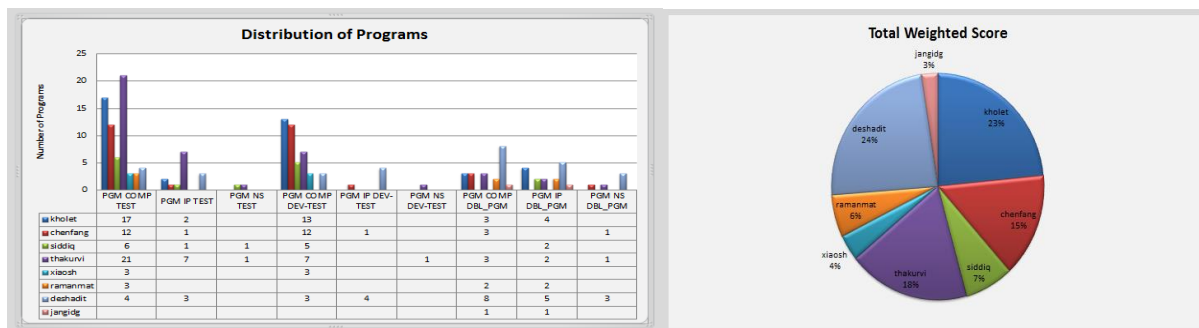


Figure 5 – Project management graphs from dashboard

CREATE CUSTOMIZED EMAIL WITH IDENTIFIED ISSUES

DPT composes a customized email for each programmer listed as a developer or validator with identified issues. The generated email contains only the identified issues for the programs which are assigned to the specific study programmer. DPT identifies programmers working on the project by reading in developer and validator columns in “Plan and Track” sheet.

CONCLUSION

The Dynamic program tracker is a very useful tool to track programming status and to ensure that clinical trial programming activities are compliant. It makes tracking process efficient and results in significant time improvement. Using the dynamic program tracker provides the overall status and also helps programmers be better programmers by identifying issues caused due to human error.

Standard folder and file naming conventions are a must for the dynamic program tracker. This enables DPT to identify developer/validator programs and respective outputs.

DPT should be run by study programmers after completion of each program to ensure that no issues are identified and periodically by programming lead/manager to ensure that programming activities are compliant and status of project is progressing as per timelines.

CONTACT INFORMATION

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