Creating a Patient Profile using CDISC SDTM

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ABSTRACT

CDISC SDTM data is the standard format requested by the FDA for clinical trial data submission. CDISC SDTM is the most complete and recognized standard available for clinical data that facilitates FDA submission.

In this presentation, we will demonstrate how to leverage the SAS® technology to create a detailed patient profile for a new study with no additional programming, once the data has been mapped to CDISC SDTM. Code components created to manipulate data in a standard format can be re-used to create standard reports for another study.

In our prototype, we show how to build a customized patient profile reporting system from CDISC SDTM data using a Unix Server. A shell script parses the sponsor's requests, which include the study id, the patient list, SDTM domains, paths for log file and output, the output filename and the format for output.

This script calls a SAS program that dynamically generates another SAS program, that is in turn automatically called to create the custom patient profile without requiring manual programming. The output is controlled by ODS, and both PDF and XML Excel formats are supported.

This presentation will be very helpful for SAS programmers interested in:

- Creating highly customized reports without requiring programming
- Learning new SAS programming skills
- Using CDISC SDTM as a data middle-tier to improve core re-usability
- Understanding the structure of a patient profile built around the SDTM model
- Promoting CDISC benefits within their organization.

INTRODUCTION

Bio-pharmaceuticals are conducting clinical trials to develop new drugs and medical devices. A trial can cost hundreds of millions of dollars and can last five to ten years. In this high cost and high risk environment, companies are rewarded with huge financial when they bring new products to market. The Biotech industry has introduced a number of innovations to speed up clinical trials. One of them is the use of Electronic Data Capture system (EDC) to collect clinical data. Not only EDC speeds up clinical trials, it also improves the communication between sponsors, sites and patients.

The next wave of innovation involves developing and creating modular and reusable tools. With the proliferation of EDC systems, it is not uncommon that multiple systems are used in the same department to manage individual studies. Because of the lack of standardization, each EDC system requires its own technology to organize, collect and store data, making it impossible to share data and tools between similar studies/trials.

Data managers develop edit checks, reports and listings to check data consistency and to ensure high quality. Because the database types and structure are different for each study, companies spend a lot of time and money implementing the same type of tools for different systems. Listings and reports programmed for one study are usually not reusable for another study without additional programming.

This paper presents a patient profile program developed for one of the top three biotechnology companies that wanted a program that could automatically generate the patient profile for any subject in any trial. This program uses SDTM tables to generate a patient profile for any subject, in any study, without requiring additional programming.

CDISC SDTM

Study Data Tabulation Model (SDTM) defines a standard structure for human clinical trial data tabulations. It provides a standardized framework for describing the information collected during clinical trials. Variable names and attributes standardization allows for reusable tools and data across multiple trials. STDM benefits the industry by providing more efficient data transfer/sharing, resulting in faster time to market.

SDTM generation is the process of transforming collected data to standardized format. Each clinical trial is unique and collected data do not have the same structure. STDM generation eases the process of generating a standardized database.

In the paper "An excel framework to convert clinical data to CDISC SDTM leveraging SAS technologies", Ale Gicqueau introduced a tool that maps any clinical database to CDISC SDTM. All mapping definitions and rules written in Excel are dynamically converted into a SAS program that performs the SDTM transformation and validation with minimum programming through a series of SAS macros.

Using these standardization techniques, it becomes easy to develop reusable tools, such as patient profiles, that can be used with any clinical trial.

PATIENT PROFILE

Patient profiles are individualized displays of patient data. They offer an opportunity to have a complete picture of the subject's status and to easily identify issues in the database. They are used to track unusual values and relationships within patient data.

The FDA does not require that the patient profile be generated and submitted since they can use PPD patient profiles to review the data. However, patient profiles are still useful and can be used as reference by different clinical departments, including biostatistics, data management, safety, clinical operations, and medical writing. They complement the edit checks and listings for data validation and cleaning. Patient profiles offer a great alternative to cross-edit checks, which are sometimes too difficult or too costly to be programmed.

Patient profiles are used to make patient safety decisions, help medical writers with patient narratives, and in data review meetings.

There are many approaches for generating patient profiles. A lot of them involve a lengthy programming effort. With this program, patient profiles can be generated with no additional programming once the data have been mapped to CDISC SDTM.

REQUIREMENTS

This program was developed to help clinical teams with their clinical trials. They wanted a program that could automatically generate the patient profile for any subject in any trial without additional programming. It had to use the SDTM tables created by the CDISC mapper.

They had some additional requirements:

- The program should identify the new and updated data since the previous program run.

- It should allow users to create the patient profile for a specific subject, a set of subjects, or all the subjects.

- Users should be able to select the domains to display.

PROGRAM

Patient profiles are created using a shell script and two SAS programs. Users' requests are entered in a command line interpreter using different parameters, described in the next paragraph. A shell script reads the command line and parses the parameters passed by the user. This shell script then calls a SAS program passing the command line parameters to the SAS program. Next, the SAS program uses the parameters to dynamically generate a new SAS program that will create the patient profile output, that is controlled by ODS.
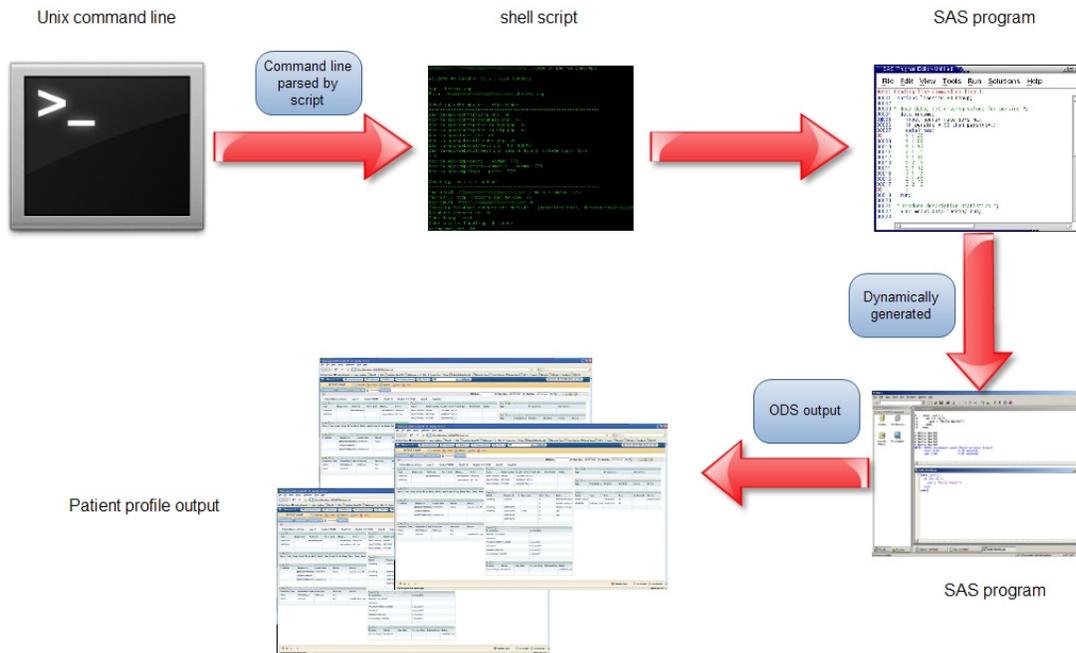
Figure 1. Program diagram. Patient profiles are created using a shell script to parse a command line.

USING THE PATIENT PROFILE

Users produce custom patient profiles using a command line. They can use multiple command parameters to customize the output. Some parameters are required for the program to run, while others are optional and allow users to choose the output they want.

Required parameter

-t ('trial'): Identifies which study to run the patient profile for.

Example:

Cp_pp –t dyonisos

This command line is the minimum needed to create the patient profile. It will create the patient profile for all the subjects enrolled in the study named "Dyonisos", generating a pdf file named _pp_auto.

Users can also select several optional parameters to create a specific report.

Optional parameters

-r ('report'): Controls the report name

Example:

Cp_pp –t dyonisos **–r** patient_profile_dyonisos

This parameter will set the name of the patient profile output file to 'patient_profile_dyonisos'. It also sets the output name in the footer.

-d ('domain'): This option allows for selection of any single panel or combination of specified panels.

Examples:

Cp_pp –t dyonisos **–r** patient_profile_dyonisos **–d** mh

Cp_pp –t dyonisos **–r** patient_profile_dyonisos **–d** "aeex aecm mh"

By default, all panels are output in each patient profile

-f ('format'): This option allows selection of Microsoft Excel format for the output.

Example:

Cp_pp –t dyonisos **–r** patient_profile_dyonisos **–f** xls

By default, the PDF format is automatically selected.

-l ('log'): Allows for specification of a directory where the SAS log file will be stored.

Example:

Cp_pp –t dyonisos **–r** patient_profile_dyonisos **–l** /onco/dyonisos/profile/log

The specified directory for the SAS log must exist otherwise the default directory will be used.

-o ('output'): This option identifies the directory where the patient profile output will be directed to.

Example:

Cp_pp –t dyonisos **–r** patient_profile_dyonisos **–o** /onco/dyonisos/output

If the output directory is not specified, the report will appear in the current directory.

-p ('panel'): This option allows for selecting a specific subject or set of subjects.

Example:

Cp_pp –t dyonisos **–r** patient_profile_dyonisos **–p** 001004

Cp_pp –t dyonisos **–r** patient_profile_dyonisos **–p** "001004 001006"

Cp_pp –t dyonisos –r patient_profile_dyonisos –p biostat/pma/selected.csv

An external file with a list of subjects can be used with the program.

-s ('split'): Creates a separate output for each study subject.

Example:

Cp_pp –t dyonisos –r patient_profile_dyonisos –sq

CONCLUSION

This program is a good example of innovation developed to create modular and reusable tools. It generates patient profiles for any subject in any trial as long as the data have been mapped to CDISC SDTM. Highly customized reports are created by simply using a command line, without requiring programming time and cost.

CDISC SDTM is used as a data middle tier. It improves code re-usability as there is no need to develop multiple versions of the same program for different studies. SAS programs using SDTM become easy to maintain, validate, and update. Many generic reports can be created using SDTM and implemented quickly for multiple studies.

REFERENCES

Framework to convert clinical data to CDISC SDTM leveraging SAS technologies, Ale Gicqueau, WUSS 2010.

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