Patient Profile, a Simple Approach

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ABSTRACT

A patient profile is a graphic display of individual patient specific information over time that helps one understand the relationships between the data for a patient. Given budget and resource restrictions, companies often cannot afford to license expensive and complex off-the-shelf patient profile software products. However, using validated analysis files, along with simple Base SAS® and SAS/GRAPH® software, you can create simple, flexible and informative, customized patient profiles. In this paper, we will present how Gilead Sciences developed and used the in-house generated patient profiles and how any company can repeat the same success.

INTRODUCTION

Summary tables present summarized statistical outputs and listings help support the tables by presenting detailed individual patient data of interest. A patient profile is a hybrid of raw data listing and graphic where the data are presented over time. By putting data of interest on the same graph, the users will be able to see the data at any given point of the study from the beginning to the end. In particular, the point at which the patient crosses from one treatment to another can be easily identified.

At Gilead Sciences (GSI), we have developed patient profiles successfully by using pre-defined derived variables and analysis files. The users first determine what information they wanted to see in the patient profile. Once we have the variables of interest derived in the analysis files, we will be able to combine them into one file and use SAS/GRAPH to produce the output, one for each patient.

Furthermore, the patient profiles developed at GSI can also be sorted or grouped by category, and further by sub-category.

Unlike many of the off-the-shelf patient profile software, the patient profile developed in-house offers flexibility in that more variables of interest can be plotted in the same graph. Within the graph, the user can also customize the symbols, plot reference ranges, or add more information at the top or at the bottom.

GILEAD'S APPROACH

Patient profile plots the variables of interest. To save time and resources, GSI utilizes validated derived variables coming from the analysis files, and which are the crucial components to build a successful patient profile efficiently.

The analysis files derive analysis variables defined in the SAP and other study related variables of interest. With all required variables pre-defined in the analysis files, one can easily combine all these variables into one file that serves as input to plot individual patient profile.

The following flow chart (Figure 1) describes the process:

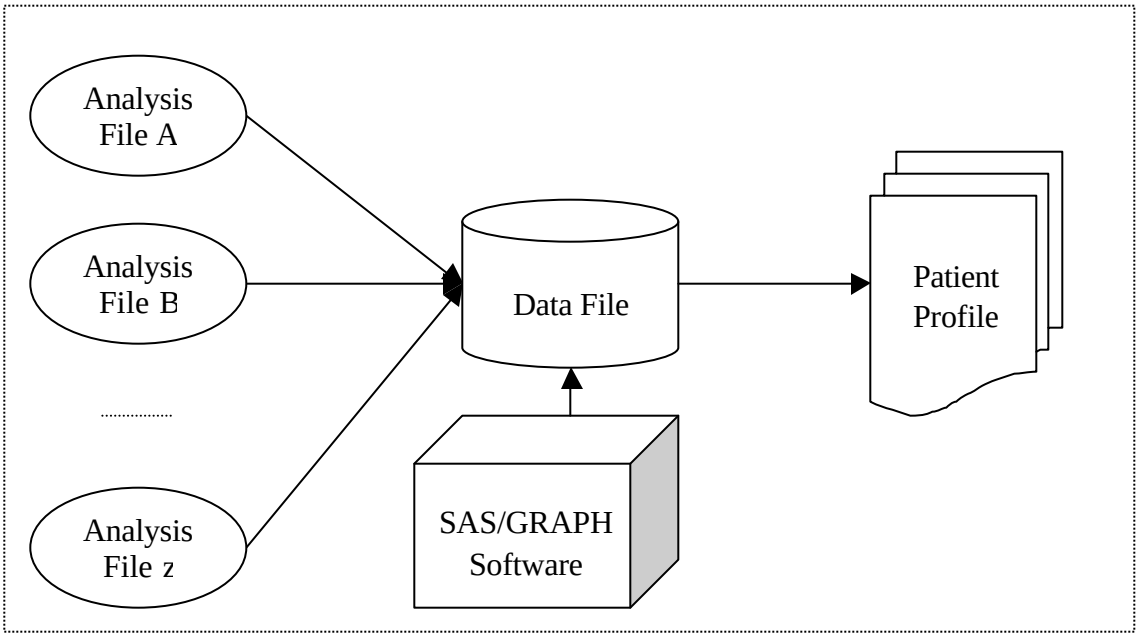

Figure 1: Patient Profile generation process

SAMPLE PROGRAM

The Data File in Figure 1 can easily be created using Base SAS by retrieving variables from analysis files and combining them together into one data set. It does not require the input dataset in any specific structure or standard (i.e., CDISC ODM or SDTM) For old studies, this may be an added benefit. Any data manipulation can also be achieved within Data File creation. The SAS/GRAPH procedure used to plot the patient profile is PROC GPLOT.

```
DATA STEPS:
<Retrieve DATA>
<Manipulate Data and Create Additional Variables if Necessary>
<Combine variables into single Data File>

<SAS/GRAPH Code>
   FILENAME statements;

   GOPTIONS statements;

   GLOBAL statements;
          <Titles and Footnotes>
           <Symbol, Axis, Legend, and Pattern for each of the variables to be
plotted>

   PROCEDURE statements;
```

SAMPLE OUTPUT

Figure 2 is a typical patient profile developed at GSI. It shows a large amount of information including 6 interest variables and 2 reference lines in a small space, allowing a viewer to see how this patient was treated over time and how the Log HBV DNA and ALT levels might have been affected (along with eAg and eAb) by the treatment regimen.

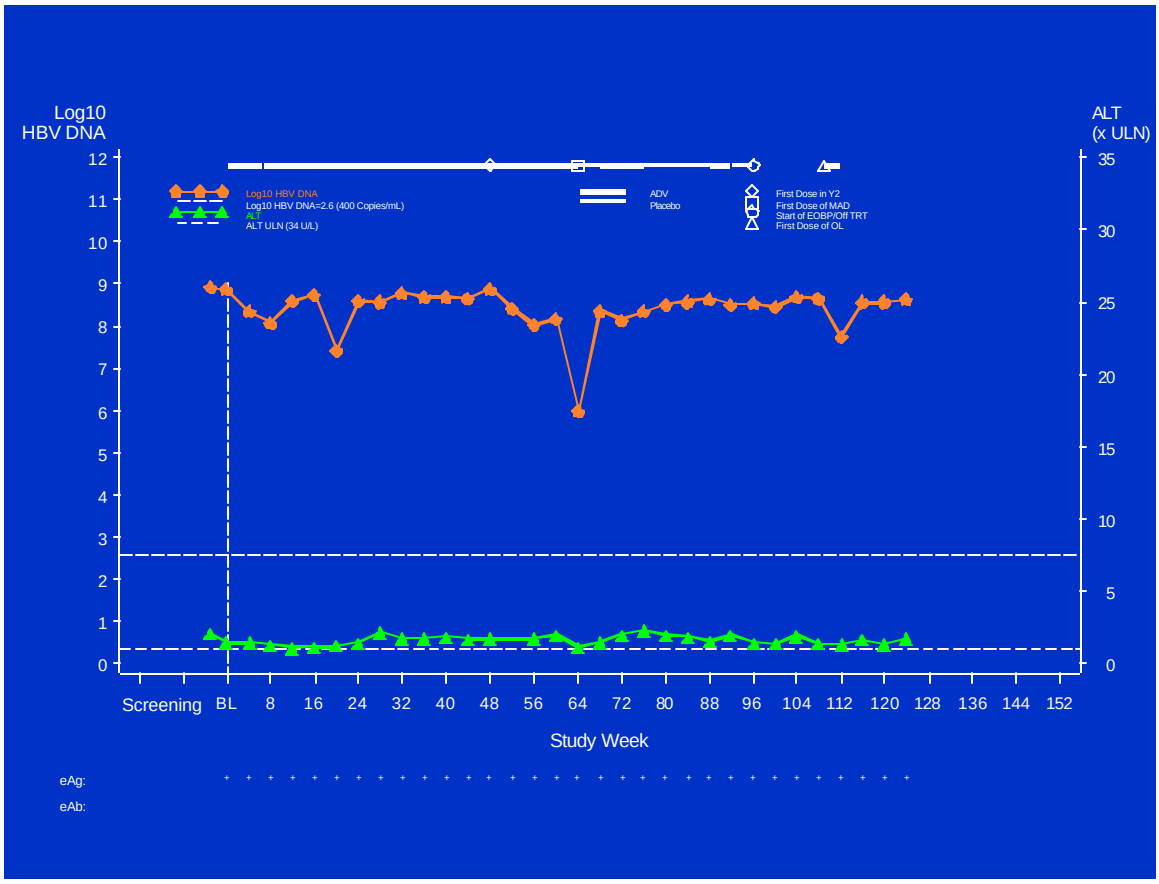

Figure 2: Sample Patient Profile (For patient 999 in study 111)

CONCLUSION

The patient profile can be easily developed in house using validated derived variables and the analysis files as the input, along with Base SAS and SAS/GRAPH as the tools. Unlike off-the-shelf products, the in-house developed patient profile can be customized based on user requirements and specifications. This provides the flexibility that users desire. Regardless what study or project needs the patient profile, once the model is set up, others can share it easily. With little training, any in-house SAS programmer can modify the code and maintain the graph, which are resource, cost and time saving for the company.

REFERENCES

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CONTACT INFORMATION

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