

A SAS Macro Application for Generating Patient-Level Reports in Clinical Studies

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ABSTRACT

In clinical observational studies, participating physicians sometimes need to obtain patient-level reports for a specific subgroup of patients to make treatment decisions. The patient-level reports often contain baseline characteristics, vital signs, adverse events and concomitant drug usages. Many analysis datasets (ADS) in pharmaceutical companies use record-based databases. Patient-level information cannot be directly derived from those databases since some patients may have multiple records in individual dataset (e.g. multiple adverse events or drug dosages). Moreover, multiple safety and efficacy related datasets are often involved to produce patient-level reports. Therefore, it comes handy to have a SAS macro to summarize patient-level information easily and quickly, with minimal formatting, and sufficient but not redundant information for clinical investigators. The macro %PATINFO described in this paper was written with that goal in mind. It can be used to generate the patient-level reports in any clinical observational study with study specific template as its key parameter. The template can be created easily with a few parameters such as variable name, variable label and dataset name. The template provides a great deal of flexibility to various data structures of different studies. %PATINFO can also be applied to non-observational clinical studies when patient-level reports are needed.

INTRODUCTION

There are occasions when physicians need patient-level reports to make treatment decisions in clinical observational studies. These reports usually contain following patient level information: baseline characteristics, vital signs, adverse events and concomitant drug usages. Since most ADS in pharmaceutical companies are record-based, it is not straightforward to produce the patient-level reports from the ADS. For example, each patient usually contains multiple records in a given dataset recording adverse events or drug dosages. It is also not common that all patient-level information is only contained in one single dataset.

In order to generate a patient-level report for a clinical study, first we need to identify the variables and related ADS which would be used to generate the report. This always can be done easily by the person (e.g. SAS Programmer) who is familiar with the ADS structure of the study. After that, we have to write long or short SAS codes to manipulate these datasets and generate the report. This step mainly depends on different people with various programming skills and styles. However, it can be done routinely as long as the variables and related datasets are identified. Therefore, it is useful to write a macro function to summarize the information quickly and efficiently, with minimal formatting, and present the report in a way which can be easily interpreted by physicians or statisticians.

The macro %PATINFO described below was written for this purpose. It can be used to generate patient-level reports in any observational or non-observational clinical study. The study specific template contains a few parameters such as variable names, variable labels and dataset names. The process of creating template is exactly the same as the one to identify the variables and related datasets. More importantly, the simple, clear and complete template aims to provide a great deal of flexibility and wide application of %PATINFO.

TEMPLATE

The template is the key parameter in %PATINFO. Different clinical studies usually have different dataset structure and names for variables. Patient-level information is also study specific. Physicians in different clinical studies usually need very specific patient-level information. The template is used to identify the data sets and related variables which would be used to generate the report. The template is simply defined with 4 parameters: Variable Label, Variable Name, Dataset Name and Comb. The display order in the final report is consistent with the template. First three parameters are easily found in the ADS according to the report requirement; comb is a newly defined parameter based on the following rules:

- comb=0 means that each record for the variable needs to be shown separately in the final report;
- comb=1 means that all records for the variable need to be combined together in the final report;

The main purpose of creating comb parameter is to show some combined patient information (e.g. drug dosages or adverse event per visit) in the final patient-level report. The comb parameter not only solves the issue of multiple records per patient but also makes the final report more readable. Therefore, the patient-level report can be shown

on one page per patient in most situations. For convenience, we choose Microsoft Excel to create the study specific template.

EXAMPLE

The standard template contains four parameters: Variable Label, Variable Name, Dataset Name and Comb. Following is a template for one sample study:

Variable Label	Dataset Name	Variable Name	Comb
Investigator	Patdat	inv	0
Patient Number	Patdat	patient	0
Gender	Patdat	gender	0
Age in Years	Patdat	age	0
Height (cm) at Baseline (Visit 2)	Patdat	htbasecm	0
Weight (kg) at Baseline (Visit 2)	Patdat	wtbasekg	0
Duration of Diabetes (yrs)	Patdat	durdiab	0
Race/Regional Origin Group	Patdat	origgrp	0
Randomization Date	Patdat	randsdte	0
Combination of Pre-treatment OAMs at Visit 2	Patdat	oralcom	0
Treatment Name	Patdat	therapy	0
Visit number-Total Daily Dose (Units)	Dose	*visit totdos_u	1
Visit number-Event-Severity	Events	*visit pttxt severtxt	1

*There should be at least one blank space between two variables.

%PATINFO

After creating the template, it is straightforward to use the macro function %PATINFO to generate patient-level information report. There are six parameters in %PATINFO:

Parameter	Purpose / Options
libpath	Input study ADS library path
template	Input study specific template excel file path
patientlist	Input patient number list (at least one blank space between two patient numbers)
keyvar	Input key variable in the study such as patient id or subject id
study	Input clinical study name
outpath	Input output file path, name and format (PDF or WORD)

EXAMLE (CONT.)

For the sample study, we have already created the template file in excel format (sampletemplate.xls) and saved it in the location C:\. All sample study ADS are saved in C:\samplelab. We need to generate a patient level report with file name Samplepatinfo in Microsoft Word format. The report needs to contain the required information of patients 10, 11 and 12 and we want to save it in the location C:\. Following is the sample SAS codes using %PATINFO to generate the patient-level report of the sample study:

```

%PATINFO (
  libpath=C:\Samplelab,
  template= C:\Sampletemplate.xls,
  patientlist=10 11 12,
  keyvar=patient,
  study=The sample Study,
  outpath=C:\Samplepatinfo.doc
);

```

OUTPUT (PATIENT 10 ONLY)

```

-----BEGIN-----
The Sample Study

Investigator
  001

Patient Number
  10

Gender
  M

Age in Years
  54.0

Height (cm) at Baseline (Visit 2)
  167.6

Weight (kg) at Baseline (Visit 2)
  79.4

Duration of Diabetes (yrs)
  13.0

Race/Regional Origin Group
  Hispanic

Randomization Date
  28APR2006

Combination of Pre-treatment OAMs at Visit 2
  Oral drug1

Treatment Name
  Treatment 1

Visit number-Total Daily Dose (Units)
  2 - 20    3 - 38    4 - 48    5 - 50    6 - 54

Visit number-Event-Severity
  3 - SKIN ULCER - Moderate    4 - OSTEOMYELITIS - Mild    4 - SKIN ULCER - Moderate
-----END-----

```

CONCLUSION

%PATINFO is a powerful SAS macro to produce patient-level reports for clinical studies. It can be used to summarize patient-level information easily and quickly, with minimal formatting, and sufficient but not redundant information for

clinical investigators. %PATINFO incorporates the template feature with a lot of flexibility. For a given clinical study, %PATINFO can save you lots of time in routine work. The template, which is a key parameter of %PATINFO, is easy to create provided you are familiar with the ADS of the study. The process of creating template is to identify variables and related datasets. The identification is essential and not very different from the usual way programmers generate the patient-level report. Once the template is ready, you can easily use %PATINFO to generate the patient-level reports containing required information such as multiple adverse events or therapy dosages, baseline characteristics, vital signs, etc...

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