

Making Patient Narrative Report Easier! – Automation Tool by C#

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ABSTRACT

In cross departmental work collaborations, we have found that medical writer tend to write patient narratives based on established templates and manually copy and paste safety data from ARGUS System into the templates. However, when faced with a large number of patients, this process is inefficient, and errors often occur when manually performing a large amount of repetitive work.

We standardize the source data into analysis results, print the results into a file, and then pass them on to medical writer. They ultimately fill in the patient narrative template to generate a document. We are now trying to concatenate the entire process and directly transfer our data source into our template. In this way, we can complete a large amount of repetitive and simple work in a short time without any "error of fatigue".

We created a tool using C # language to complete this process. C # is a language developed by Microsoft, so it is very easy to use it to generate and process a WORD document.. Due to the various data sources we often face, we will simply standardize the data before passing it on to tools to run. We will filter and organize the SAE data we need according to a standard. However, for SAS programmers, this should be a simple matter.

INTRODUCTION

The patient narrative report is a very important part of CSR. In order to support this part of the content, SAS programmer needs to present some SAE related information in the table. We send this part of the results to medical writers, who will compile the data results into the patient narrative report. In this cross departmental collaboration, we observed that medical writers used fixed templates and manually copied and pasted this information into their report templates. In fact, the entire process can be completed easily through programming, which not only saves a lot of time but also avoids errors that may occur during the manual pasting process.

For SAS programming, the above process mainly need to learn how the entire process is arranged and how to automatically fill the data in outputs into the medical writing template through C # during this process. Next, we will introduce them step by step.

PROCESS



As shown in the figure, to establish an automated patient narrative process, we first need to have a stable case report template. We check the data we need in the template, and then we create an specification to record how we collect this data and the presentation method of the data; Next is to derive the original data into outputs using SAS EG, here we use an EXCEL as an intermediate process to present these results. Finally, we write the derived data into the template through C# to generate a patient narrative report.

STANDARD DATA FORMAT

1.The data source to be extracted from the report has been marked and highlighted. We need to extract this information from the original data and then derive it into our defined standard format.

患者编号: XX

队列名称: XX

研究治疗: 药物 A (xx mg QD 口服)

发生事件类型:

人口统计学: X 岁, 种族, 性别, 身高 X cm, 体重 X kg, 体重指数 X kg/m²

首次接受研究药物的时间: XXXX-XX-XX (研究第 X 天)

末次接受研究药物的时间: XXXX-XX-XX (研究第 X 天)

不良事件:

首选术语 / 研究者报告术语	开始时间(研究日) / 结束时间(研究日)	严重程度	至事件发生时总暴露时间(天)	最近一次用药至事件发生的时间(天)	相关性	采取措施	转归
XXX	XXXX-XX-XX (研究第 X 天) XXXX-XX-XX (研究第 X 天)	X 级	XXX	XXX	XXX	XXX	XX

对于严重不良事件, 表格中的“开始时间”定义为严重不良事件的开始时间。

患者<性别>, <年龄>岁, 于<XXXX 年 XX 月 XX 日>签署知情同意书, 在<研究中心名称>参加本研究, 被分配入<队列名称>队列接受药物 A (xx mg QD 口服) 治疗, 首次接受研究药物的时间是<XXXX 年 XX 月 XX 日>。

该患者初次诊断肿瘤为 XX, 原发病灶部位为 X, 首次诊断于 XXXX 年 XX 月 XX 日。筛选时 TNM 分期为 XX, 转移情况为 XX, 首次诊断转移于 XXXX 年 XX 月 XX 日。

2. We organize the information used in the template into outputs. Before that, we first define a specification to record the source and derivative form of this information.

Dataset Name	Variable Name	Variable Label	Variable Type	Variable Length	Code list/Controlled Terms	Source/Derivation	Key
OVERALL	SUBJID	患者编号	字符型	15	非空字符串	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
OVERALL	AESDTH	导致死亡不良事件	字符型	1	"X" or 空	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
OVERALL	DTHFLON	治疗期间死亡	字符型	1	"X" or 空	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
OVERALL	SAEOTH	其他严重不良事件	字符型	1	"X" or 空	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
OVERALL	AEWITHD	导致永久停药的不良事件	字符型	1	"X" or 空	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
OVERALL	AEPD	方案规定的特殊事件	字符型	1	"X" or 空	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	SUBJID	患者编号	字符型	15	非空字符串	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	COHORT	队列	字符型	100	非空字符串	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	ARM	治疗组别	字符型	100	非空字符串	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	AETYPE	发生事件类型	字符型	100	仅包含导致死亡不良事件、治疗期	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	AGE	年龄	字符型	15	数字	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	RACE	种族	字符型	40	非空字符串	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	NATION	民族	字符型	40	非空字符串	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	SEX	性别	字符型	15	男性、女性	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	HEIGHT	身高	字符型	15	数字	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	WEIGHT	体重	字符型	15	数字	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	BMI	体重指数	字符型	15	数字	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	TRTSDTC	首次接受治疗	字符型	40	yyyy-mm-dd (研究第x天)	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	TRTEDTC	末次接受治疗	字符型	40	yyyy-mm-dd (研究第x天)	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	
DM	RFICDTC	签署知情	字符型	40	yyyy-mm-dd	具体衍生方法<来自RAWDATA or SDTM or ADAM...>	

3. The resulting dataset is presented in an Excel spreadsheet, as shown in the following figure:

A	B	C	D	E	F	G	H	I	J	K	L	
患者编号	队列	治疗组别	发生事件类型	年龄	种族	民族	性别	身高	体重	体重指数	首次接受治疗	末次
10011001	队列1	研究用药A	导致死亡不良事件，导致永久停药的不良事件	64.5	亚裔		女性	151	55	24.1	2020-06-28（研究第1天）	2020-08-31
10021001	队列2	研究用药A	治疗期间死亡，其他严重不良事件	64.8	亚裔		男性	165	60	22	2020-08-04（研究第1天）	2020-10-27
10031001	队列3	研究用药A	其他严重不良事件，方案规定的特殊事件	53.3	亚裔		男性	170	79	27.3	2020-06-17（研究第1天）	2023-02-28

In this way, we have established a standard production process to prepare the data required for automation of our patient narratives. We can complete the process of creating a dataset using SAS EG, which is similar to creating an SDTM or ADAM dataset. The SAS code used in the middle is relatively simple, I won't show it more.

AUTOMATION TOOL BY C#

This is a user interface (UI):

1. Import a template parameter configuration file
2. Import derived output

The screenshot shows the PtNarr application window. It has a title bar with standard Windows controls and a 'Hot Reload' button. Below the title bar, there are two input fields for file paths, each with a corresponding button:

- Path: `C:\Users\dingpan\Desktop\myshare\Dingpan_20230601_pharmsug\2019-012-00ch1_config.txt` with a `config` button.
- Path: `C:\Users\dingpan\Desktop\myshare\Dingpan_20230601_pharmsug\patientNarrative.xlsx` with a `data` button.

Below these fields is a large text area containing a list of variables and their corresponding codes, such as:

- 插入段落: 患者编号:DM\$A
- 插入段落: 队列名称:DM\$B
- 插入段落: 研究治疗:DM\$C
- 插入段落: 发生事件类型:DM\$D
- 插入段落: 人口统计:DM\$E岁, DM\$F, DM\$H, 身高DM\$Icm, 体重DM\$J kg, 体重指数 DM\$K kg/m2
- 插入段落: 首次研究药物的时间:DM\$L
- 插入段落: 末次研究药物的时间:DM\$M
- 插入段落: 不良事件:
- 插入表格:AE\$A

At the bottom of the window, there is a status bar with the following text:

- 7/14/2023 6:23 Import configuration file
- 7/14/2023 6:23 Import data file
- 7/14/2023 6:23 Writing a report

A `Launch` button is located in the bottom right corner of the window.

1. Let's learn the relevant code for C #, this part requires you to have at least a basic understanding of the C#(or C++) language.

C # mainly involves two key parts, one is data import, and the other is how to write WORD. The UI drawing section uses WPF's xaml syntax. We will not explain UI drawing here. You only need to simply learn the basic syntax of xaml to draw it.

```
//0- 读取数据源
OleDbConnection OleConn;
DataSet dsSource = new DataSet();

string excelPath = @"C:\Users\dingpan1\Desktop\c#\mysample1.xlsx";
OleConn = new OleDbConnection("Provider=Microsoft.ACE.OLEDB.12.0;" + "Data Source=" + excelPath + ";"
    + ";Extended Properties=\\"Excel 12.0;HDR=YES;IMEX=1\\"");
OleConn.Open();

string[] sheet = { "OVERALL", "DM", "AE", "MH", "CM" };
for (int i = 0; i < sheet.Length; i++)
{
    string sql = string.Format("SELECT * FROM [{0}]{1}", sheet[i], "$");
    OleDbDataAdapter OleDaExcel = new OleDbDataAdapter(sql, OleConn);
    DataTable dt = new DataTable();
    dt.TableName = sheet[i];
    dsSource.Tables.Add(dt.Copy());
    OleDaExcel.Fill(dsSource.Tables[sheet[i]]);
}

OleConn.Close();
```

Display 1. Using OleDb to import EXCEL

Create a DataSet object in C #, and then use the OLEDB procedure to read the Excel table into and store it in the DataTable object, and add all DataTables to the DataSet.

```
private void btConfig_Click(object sender, RoutedEventArgs e)
{
    OpenFileDialog dialog = new OpenFileDialog();
    dialog.Multiselect = false; //该值确定是否可以选多个文件
    dialog.DefaultExt = ".txt"; //该值确定是否可以选多个文件
    dialog.Title = "Select a folder";
    dialog.Filter = "Text documents(.txt)|*.txt";
    if (dialog.ShowDialog() == true)
    {
        tbConfig.Text = dialog.FileName;

        string logpath = tbConfig.Text;
        if (File.Exists(logpath))
        {
            FileStream fs = new FileStream(logpath, FileMode.Open, FileAccess.Read);
            StreamReader sr = new StreamReader(fs, Encoding.Default);

            string sText = sr.ReadToEnd();
            sr.Close();
            fs.Close();

            rtbConfig.Selection.Text = sText;
        }
    }
}
```


Display 2. Using FileStream to import template config file

Create an event, click the button to select a configuration file, then read the configuration file into C # using a text stream and display it in the UI interface

```
//开始写narrative
//1.打开一份word文档
MSWord.Application wordApp;
MSWord.Document wordDoc;
wordApp = new MSWord.Application();
wordApp.Visible = true;
wordDoc = wordApp.Documents.Add(ref Nothing, ref Nothing, ref Nothing, ref Nothing);

//1.0- word全局设置
wordApp.Options.CheckGrammarWithSpelling = false;//关闭语法检查
wordApp.Options.CheckSpellingAsYouType = false;//关闭语法检查
wordApp.Options.CheckGrammarAsYouType = false;//关闭语法检查

wordDoc.PageSetup.PaperSize = MSWord.WdPaperSize.wdPaperA4;//设置纸张样式为A4纸
wordDoc.PageSetup.Orientation = MSWord.WdOrientation.wdOrientPortrait;//排列方式为垂直方向

wordDoc.PageSetup.LeftMargin = 57.0f;//页边距
wordDoc.PageSetup.TopMargin = 57.0f;
wordDoc.PageSetup.RightMargin = 57.0f;
wordDoc.PageSetup.BottomMargin = 57.0f;
```

Display 3. Using Microsoft.Office.Interop.Word

Create a word application and then create a word document that can be set globally.

```
//1.3- 写每个病人的病例叙述
//1.3.1- 人口学信息
wordApp.Selection.InsertBreak();//新建一页开始写
wordApp.Selection.Delete();

wordApp.Selection.set_Style("Heading 2");
wordApp.Selection.ParagraphFormat.LineSpacing = 12f;//设置文档的行间距
wordApp.Selection.Font.Name = "Times New Roman";
wordApp.Selection.Font.Size = 12;
wordApp.Selection.Font.Color = MSWord.WdColor.wdColorBlack;
wordApp.Selection.ParagraphFormat.Alignment = MSWord.WdParagraphAlignment.wdAlignParagraphLeft;//设置居左
wordApp.Selection.Font.Bold = 0;//不加粗

wordApp.Selection.TypeParagraph();
wordApp.Selection.Font.Bold = 1;
wordApp.Selection.TypeText("受试者编号：");

wordApp.Selection.MoveLeft(MSWord.WdUnits.wdWord, 2, MSWord.WdMovementType.wdExtend);
wordApp.Selection.Bookmarks.Add("ID" + dsSource.Tables["DM"].Rows[0][0].ToString(), wordApp.Selection.Range);
wordApp.Selection.MoveRight(MSWord.WdUnits.wdWord, 1);
wordApp.Selection.Font.Bold = 0;
wordApp.Selection.TypeText(dsSource.Tables["DM"].Rows[0][0].ToString());
```

Display 4. Using Selection.TypeText

Use selection.paragraph() method statement to inset a paragraph, and use selection.typetext to add content text.

```
//1.3.1- SAE表格
MSWord.Table AETable = wordDoc.Tables.Add(wordApp.Selection.Range, dsSource.Tables["AE"].Rows.Count, dsSource.Tables["AE"].Columns.Count
    , MSWord.WdDefaultTableBehavior.wdWord9TableBehavior, MSWord.WdAutoFitBehavior.wdAutoFitFixed);
AETable.ApplyStyleHeadingRows = true;
AETable.ApplyStyleLastRow = false;
AETable.ApplyStyleFirstColumn = true;
AETable.ApplyStyleLastColumn = false;
AETable.ApplyStyleRowBands = true;
AETable.ApplyStyleColumnBands = false;

AETable.AllowAutoFit = false; //设置列宽
AETable.Columns.PreferredWidthType = MSWord.WdPreferredWidthType.wdPreferredWidthPercent;
AETable.Columns[1].PreferredWidth = 15.7f;
AETable.Columns[2].PreferredWidth = 21.7f;
AETable.Columns[3].PreferredWidth = 6.1f;
AETable.Columns[4].PreferredWidth = 11.4f;
AETable.Columns[5].PreferredWidth = 12.2f;
AETable.Columns[6].PreferredWidth = 11.2f;

for (int i = 0; i < AETable.Rows.Count; i++)
{
    for (int j = 0; j < AETable.Columns.Count; j++)
    {
        if (i == 0)
        {
            AETable.Rows.First.HeadingFormat = -1;
            AETable.Rows[i].Cells[j].Range.Text = dsSource.Tables["AE"].Columns[j].ColumnName;
        }
        else
        {
            AETable.Rows.HeadingFormat = 0;
            AETable.Rows[i].Cells[j].Range.Text = dsSource.Tables["AE"].Rows[i][j].ToString();
        }
    }
}
```

Display 5. Using Microsoft.Office.Interop.Word.Table

Using a loop to pass the DataTable object to the Word.Table object, insert the AE table into Word in this way.

```
//1.3.3- 人口学描述段落
wordApp.Selection.EndKey(MSWord.WdUnits.wdStory);
wordApp.Selection.TypeParagraph();//新起一个段落
wordApp.Selection.ParagraphFormat.FirstLineIndent = 24;//首行缩进的长度
wordApp.Selection.ParagraphFormat.Alignment = MSWord.WdParagraphAlignment.wdAlignParagraphLeft;//段落对齐居左
wordApp.Selection.TypeText(String.Format("患者{0}, {1}岁, 于{2}签署知情同意书, 在{3}参加本研究, " +
    "被分配至{4}队列接受药物A治疗, 首次接受研究药物的时间是{5}。"));
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    ));

//1.3.4- 初次诊断肿瘤病史
wordApp.Selection.TypeParagraph();//新起一个段落
wordApp.Selection.ParagraphFormat.FirstLineIndent = 24;//首行缩进的长度
wordApp.Selection.TypeText(String.Format("该患者初次诊断肿瘤为{0}, 原发病灶部位为{1}, 首次诊断于{2}, 筛选时TNM分期为{3}, " +
    "转移情况为{5}, 首次诊断转移时间为{6}。"));
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    , dsSource.Tables["DM"].Rows[0][12].ToString()
    ));
```

Display 6. Insert an entire paragraph

When inserting an entire paragraph, we use Selection.ParagraphFormat.FirstLineIndent to add an indentation, and then use the String.Format() method to write the entire paragraph into word.

CONCLUSION

Overall, we can create and implement more automated tools through the methods in the article, and I share with this patient that automation is a relatively easy and understandable example. This includes several key points that we must learn. The first point is to establish a standard template for automated speech, through which we can derive the data source into a standardized data form. Secondly, an automated filling process can be achieved through tools. From the paper, we can see that C# and Office are very friendly, and the code looks very convenient. This is also why I recommend using C# to handle Excel and Word. However, in reality, the entire process can be achieved by only using SAS language.

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CONTACT INFORMATION

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BASIC INSTRUCTIONS

WRITING GUIDELINES

Writing style

- Use active voice. (Use passive voice only if the recipient of the action needs to be emphasized.) For example:
The product creates reports. (active)
Reports are created by the product. (passive)
- Use second person and present tense as much as possible. For example:
You get accurate results from this product. (second person, present tense)
The user will get accurate results from this product. (future tense)
- Run spellcheck, and fix errors in grammar and punctuation.

Citing references

All published work that is cited in your paper must be listed in the REFERENCES section.

If you include text or visuals that were written or developed by someone other than yourself, you must use the following guidelines to cite the sources:

- If you use material that is copyrighted, you must mention that you have permission from the copyright holder or the publisher, who might also require you to include a copyright notice. For example: "Reprinted with permission of SAS Institute Inc. from *SAS® Risk Dimensions®: Examples and Exercises*. Copyright 2004. SAS Institute Inc."
- If you use information from a previously printed source from which you haven't requested copyright permission, you must cite the source in parentheses after the paraphrased text. For example: "The minimum variance defines the distance between cluster (Ward 1984, p. 23)

TIPS FOR USING WORD

These instructions are written for MS Word 2007 and MS Word 2010. The steps are similar for MS Word 2003.

To select a paragraph style

1. Click the **HOME** tab. The most common styles in your document are displayed in the top right area of the Microsoft ribbon. If you don't see a style that you want, click the slanted down arrow at the bottom right corner of the Styles area, and scroll through the list. The main styles for this template are headings 1 through 4, PaperBody, and Caption. Avoid using other styles.
2. To change a paragraph style, click the paragraph to which you want to apply a style, and then click the style that you want in the ribbon.
3. PaperBody (used for most text) is automatically applied when you press Enter at the end of any heading style or the Caption style.

To insert a caption

1. Click **REFERENCES** on the main Word menu.
2. Click **Insert Caption**.
3. Select the **Label** type that you want.
4. Click **OK**.

To insert a cross-reference

1. Click **REFERENCES** on the main Word menu.
2. Click **Cross-reference**.
3. In the **Reference type** list box, select Heading, Figure, Table, Display, or Output.
4. For a heading:
 - a. In the **For which heading** list, select the heading that you want.

- b. From the **Insert reference to** list, select **Heading text**.
5. For a figure, table, display, or output:
 - a. In the **For which caption** list, select the caption that you want.
 - b. From the **Insert reference to** list, select **Only label and number**.

To insert a graphic from a file

1. Click **INSERT** on the main Word menu.
2. Click **Picture**.
3. In the Insert Picture dialog box, navigate to the file that you want to insert.
4. When the name of the file that you want to insert is displayed in the **File name** box, click **Insert**.