ABSTRACT
This paper presents an innovative approach of using ODS with the RTF destination for automatically generating a customized Table of Contents in WORD with hyper links to hundreds of tables from the Section 14 in Clinical Study Reports (CSRs). This approach has dramatically reduced the amount of errors that are inevitable in the manual process situation and also greatly expanded the contents feature in comparison with the HTML approach and significantly reduced the amount of time in CSR writings.

INTRODUCTION
This paper will describe the challenging task of putting together all tables for the Section 14 with Table of Contents (TOC) feature in preparation of a CSR and why and how the difficulty can be solved with the aid of ODS/RTF. Throughout the duration of this paper, ODS destination RTF is assumed unless indicated otherwise. Familiarity with proc report and basic ODS concepts as well as ODS template is preferred for better understanding of the technical nature of this paper.

THE QUESTION
It's not an easy task for programmers to generate a friendly TOC for all output tables, listings, and figures. Section 14 in CSR contains all tables referenced but not included in the body of the report. Depending on the requirements of analysis in a typical clinical study hundreds of tables may be included in this section for the sake of completeness. It is inevitably a process involving intense labors and prone for human errors due to the manual work nature; let alone the effort ensuring all hyperlinks correctly linked to the right output files. Following is a brief description of the conventional manual process (without loss of generality, the captain-based TOC approach will be used for illustration purpose):

1) Concatenating tables – this may take a while if there’re lots of tables to be put together;
2) Setting caption style for the title of each table – this may take even longer since the style needs to be applied to the title of each individual table;
3) Inserting a TOC and formatting whenever necessary – this step is straightforward after 1) and 2) are done properly.

Our goal in this paper will aim at addressing a NEW programmatic solution for the second step. In the first step VBA scripts are usually implemented relatively quickly in WORD through the built-in macro recorder [2]; in the second step, a customized ODS approach combining ODS reporting and RTF in-line formatting has been implemented for a novel solution.

CAPTION AND TOC
WORD has a nice feature of automatically generating TOC based on caption styles. From the main menu choose Insert -> Index and Tables -> Table of Contents -> Options, then select TOC level associated with caption style as follows –
RTF AND STYLESHEET

In order for programmatically generating caption style for WORD outputs knowledge of how to customize a stylesheet in RTF destination is very helpful.

The stylesheet control word introduces the style sheet group, which contains definitions and descriptions of the various styles used in the document. In RTF, a style is a form of shorthand used to specify a set of character, paragraph, or section formatting. Commonly used styles are \sN and \csN for paragraph and character styles respectively [3].

The RTF mark-up code \s15 caption; assigns caption style to text strings in the paragraph following the control word \s15. In this paper, the number 15 in the control word is conveniently used as a style handler for pointing to the caption style, although other integer numbers will work too.

THE ODS SETTINGS

The settings comprise of four parts: template, ODS path, odson and odsoff.

TEMPLATE

Modify styles.rtf to suit your specific requirement. Often times the change has to do with table borders. This is demonstrated as follow:

```
proc template;
  define style tStyle/store=work.templ;
  parent=styles.rtf;
  style Table from output /
    ... rules=&ru frame=&fr;
```

Ru=groups Fr=void are used for the output in this paper. The output table will hide grids and borders.

ODSPATH

Invoke first the modified template:

```
ods path work.templ ...%
```

Specify output destination:

```
%let odspath=...
```

ODSON

A macro to open output destination:

```
ods rtf file="&odspath" wordstyle='\s15 caption;'
```

The wordstyle parameter in the above ODS statement generates a stylesheet containing mark-up code for caption. This feature is experimental in version 9.1 and production in version 9.2 [1].

ODSOFF

A macro to close output destination:

```
ods rtf close;
```

THE ODS/RTF SOLUTION

After the above settings for ODS environment are ready, the only additional thing that needs to be done to make the TOC automatic programming work is to add a piece of mark-up code in the title statement. The following is a simplified example based on PROC REPORT:

```
Proc report data=ONE nowd headline spacing=2 split='+';
  Col ("\s={font_size=6pt}\R/RTF\s15" This is a test\R/RTF\par" X);
  Define X/group "" style={(cellwidth=1in just=c)};
  Title ' ';
quit;
```

In this example, the data set ONE includes a variable named X. X is reported with header “This is a test” from the Column statement and because the inline format \R/RTF\s15 assigns caption attribute, X’s header will be used in generating a TOC according to the aforementioned method.
Another common way to mark up titles is in the title statement as follows:

```sas
Proc report data=ONE nowd headline spacing=2 split='+';
    Col (X);
    Define X/group '' style={cellwidth=1in just=c};
    Title '\R/RTF''\s15''S={font_size=12pt} This is a test\R/RTF''\par'';
quit;
```

As seen from the above example, additional attributes can be added to the specified character string for enhancing format in the final TOC.

After using VBA macro to concatenate all tables or other output files that are referenced in study analyses, a user friendly and formatted TOC will be generated by using the caption information already marked up within each individual file.

DISCUSSION AND CONCLUSION
Three methods of creating TOC were presented in [4], of which the second method was based on wordstyle option in the ODS statement and was similar to the approach in this paper. This method is the most code friendly one because programmers can write codes to control formatting of the final TOC. Unlike the mark-up technique in [4] which was based on heading styles, this caption-based technique for marking text strings avoids confliction with other attributes that already exist in the CSR template; therefore is enhanced and implemented in this paper.

Furthermore, efficient macro modules have been developed in order to streamline the process of generating large number of output files and provide a systematic ODS/RTF solution for creating TOC for Section 14 in CSRs.

In conclusion, it has been shown that the well-known RTF inline formats feature plus caption stylesheet feature together provide a novel approach to automatically generating a WORD friendly TOC. This technique has greatly reduced the amount of time in the preparation of Section 14.

REFERENCES

CONTACT INFORMATION
Your comments and questions are valued and encouraged. Contact the author at:

Haibin Shu
TEVA PHARMACEUTICAL INDUSTRIES LTD
11th Floor, One Belmont Ave
Bala Cynwyd, PA 19004
Work Phone: (610)747-2688
Fax: (610)747-6615
E-mail: hshu@barrlabs.com
Web: www.tevpharm.com

SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries. © indicates USA registration. Other brand and product names are trademarks of their respective companies.