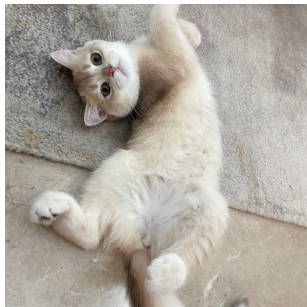


Single Day Event

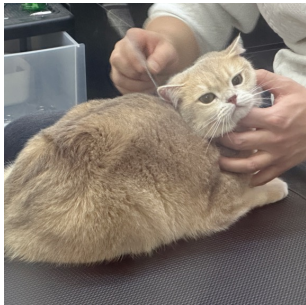
LaTeX Implementation in Reviewer's Guide
Shujiang (Joanne) Zhang,
Fosun Pharma



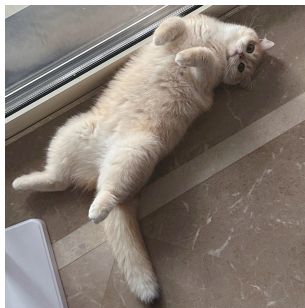
Introduce my cat...



Twisted



Messy



Disorderly

L^AT_EX



Elegant



Agenda

- Background
- Introduction to LaTeX
- How to Implement Reviewer's Guide Automation via LaTeX
- Conclusion
- Reference



Background

Review's guide is a vital component of a successful submission for regulatory review in the pharmaceutical industry.

For generating a reviewer's guide, there's no "one-size-fits-all" software tool. Commonly used software includes:

- Microsoft Word: User-friendly and commonly used, but can be cumbersome for larger, more complex documents, formatting consistency can be an issue and not ideal for version control.
- PDF Editors: Good for final submission due to portable and universally readable format, but limitations in editing and lack of ability to track changes. Few people program PDF directly using a programming language (like Python, via PyPDF2 or the pdfminer library)

Introduction to LaTeX

L^AT_EX

A high-quality typesetting system. Widely used for scientific and mathematical documents. Flexible and powerful, enabling the creation of well-structured and well-formatted documents

Key Features



Automated
Formatting



Customization



Consistency

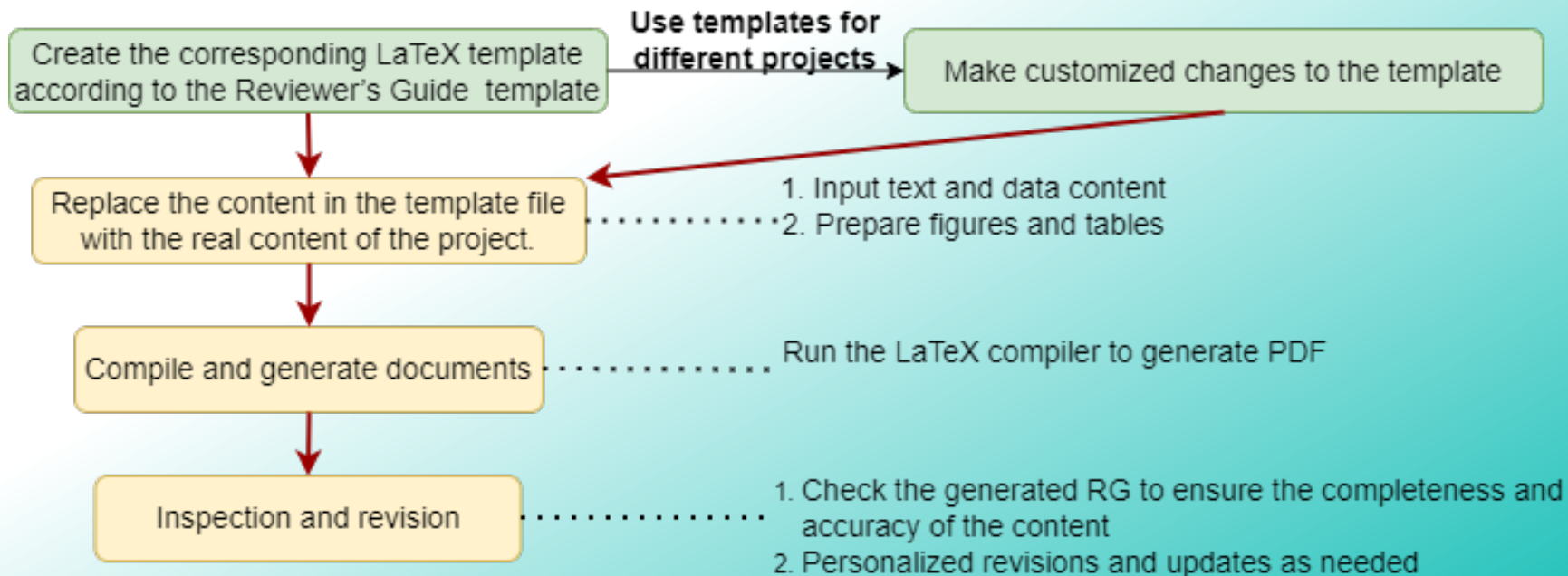


Integration

Advantages in RGs: Efficiency, Quality Assurance, Designing by Code



How to Implement Reviewer's Guide Automation via LaTeX?



Create the LaTeX Template

Prepare format documents, tables and figures that will be used in LaTeX template

Format documents:

- Use predefined styles and templates to ensure document consistency
- When you change styles, just change the template and the styles for the entire document are automatically updated



preamble.tex



```
\usepackage{fontspec} %Times New Roman;  
\usepackage{titlesec} %Change the fontstyle of section;  
\usepackage{fancyhdr} %fancyhdr for header and footer;  
\usepackage{titletoc} %titletoc to adjust TOC;
```

Tables and figures

- Use commands such as `\includegraphics{figure1.jpg}` to precisely control image size and position. Titles and numbers for figures and tables are updated automatically



Create the LaTeX Template

Create a standard LaTeX template of Reviewers Guide

- Create the corresponding LaTeX template according to the Reviewer's Guide template
- Add the conventions from both review's guide completion guidelines and sponsor requirement as notes to the standard LaTeX template

LaTeX

```
%1.1;
```

```
\subsection{目的}
```

本文档提供了分析数据集和术语的背景信息，是对数据说明文件 (define.xml) 的额外补充。此外，本文档还提供了 ADaM 一致性评价检查结果的汇总。

```
\input{notes/note_1.1.txt}
```

PDF

1.1 目的

本文档提供了分析数据集和术语的背景信息，是对数据说明文件 (define.xml) 的额外补充。此外，本文档还提供了 ADaM 一致性评价检查结果的汇总。

Notes:

This required section states the purpose of the ADRG. Please refer to the ADRG Template for standard text. If legacy tabulation was converted to SDTM and then to ADaM, or legacy analysis data was converted to ADaM, include the sentence in the template related to the conversion.



Replace the Content in the Template File

Data and Content Input:

- Replace the data and text in the template file with the real content of the project
- Tables
 - Excel2LaTeX: an Excel add-in that converts excel tables into LaTeX table code
 - VBA: automate the conversion of excel tables into sponsor-specific LaTeX table code, within VBA interface (like Microsoft Excel), write macros that output LaTeX code

	A	B	C	D	E	F
1	Please Select Output Path					
2	SDRG Path	E:\02-项目\mon-projects\2023\RG\files\sdrg			SDRG	
3	ADRG Path				ADRG	
4						
5	RG Type	Sheet Name	Status	Comments	RUN	
6		1.2缩略语	Not Completed	没有定义RG类型: 例如A_XX或者S_XX;		
7	SDRG	SUPP	Completed			
8	SDRG	1.2缩略语	Completed			
9	SDRG	1.3研究数据标准和词典清单	Completed			
10	SDRG	2.3试验设计数据集	Completed			
11	SDRG	3.3注释病例报告表	Completed			
12	SDRG	3.4SDTM受试者域	Completed			
13	SDRG	4.2问题汇总	Completed			
14	SDRG	附录A排标准	Completed			
15	ADRG	1.3研究数据标准和词典清单	Not Completed	没有指定输出路径;		
16	ADRG	2.2案设计中与ADaM相关的概念	Not Completed	没有指定输出路径;		
17	ADRG	3.1核心变量	Not Completed	没有指定输出路径;		



Replace the Content in the Template File

Data and Content Input: Tables via VBA

- Extract the information from the source data or specified path for special tables
 - Read Pinnacle 21 report for issue summary table
 - Obtain programs name from specified path for ADaM programs table
 - Read SDTM DDT for SUPP variables table...

LaTeX

```
\begin{longtable}[c]{|p{3cm}|p{3cm}|p{8.54cm}|} \hline
\fstablebkground {\bf 程序} & {\bf 输出} & {\bf 使用的宏} \\\hline
adae.txt & adae.xpt & Please enter macro used in adae.sas \\\hline
adeff.txt & adeff.xpt & Please enter macro used in adeff.sas \\\hline
adrs.txt & adrs.xpt & Please enter macro used in adrs.sas \\\hline
adsl.txt & adsl.xpt & Please enter macro used in adsl.sas \\\hline
adtte.txt & adtte.xpt & Please enter macro used in adtte.sas \\\hline
\end{longtable}
```

VBA

A	B	C	D	E	F	G
3	3	8.54				
程序	输出	使用的宏				
adae.txt	adae.xpt	Please enter macro used in adae.sas				
adeff.txt	adeff.xpt	Please enter macro used in adeff.sas				
adrs.txt	adrs.xpt	Please enter macro used in adrs.sas				
adsl.txt	adsl.xpt	Please enter macro used in adsl.sas				
adtte.txt	adtte.xpt	Please enter macro used in adtte.sas				

7.1 ADaM 程序

程序	输出	使用的宏
adae.txt	adae.xpt	Please enter macro used in adae.sas
adeff.txt	adeff.xpt	Please enter macro used in adeff.sas
adrs.txt	adrs.xpt	Please enter macro used in adrs.sas
adsl.txt	adsl.xpt	Please enter macro used in adsl.sas
adtte.txt	adtte.xpt	Please enter macro used in adtte.sas



Compile and Generate Documents

Inspection and Revision

Compile and generate documents

- Many text editors available for LaTeX compilation: Rstudio, VS code, TeXworks, etc.
- Online platforms that support LaTeX: Overleaf
- Be used with version control tools (such as Gitlab) to facilitate tracking changes and collaborative work.

Inspection and revision:

- Check the generated RG to ensure the completeness and accuracy of the content
- Personalized revisions and updates as needed



Demo

File Edit Selection View Go Run ... Search

LATEX ...

COMMANDS

- Recipe: XeLaTeX
- Recipe: PDFLaTeX
- Recipe: BibTeX
- Recipe: LaTeX...
- Recipe: xelatex...
- Recipe: pdflat...
- View LaTeX PDF
- View in VSCod...

STRUCTURE

- 3.2 治疗组变量
- 3.3 需要特定分析...
- 3.4 访视时间窗、...
- 3.5 缺失数据填补...
- 4 分析数据的创建...
- 4.1 拆分数据集

SNIPPET VIEW

Symbols TikZ

Search

All

$\alpha \beta \gamma \delta \epsilon \zeta \eta$

$\theta \vartheta \iota \kappa \lambda \mu \nu \xi$

C:\Users\zhangshuijiang\Desktop>RG工具>adrg_cn_v1.0>%*% adrg.tex

```
1 %*****
2 %Reporting Efforts : Develop ADRG template in Late
3 %Program Name      : adrg.tex
4 %Language/Version  : LaTeX
5 %Short Description  : Standardized ADRG template
6 %Author            : liulin5
7 %Date              : 24OCT2022
8 %Input             : NA
9 %Output            : adrg.pdf
10 %Modification History:
11 %Rev  Modified By   Date      Description
12 %*****
13
14 \documentclass[11pt]{article}
15
16 \newcommand{\fswaterprint}{Internal Version 1.0} %<No
17 \newcommand{\fsfile}{分析数据审阅说明} %<Note: No need
18 \newcommand{\fssponsor}{申办方名称} %<Note: Update spc
19 \newcommand{\fsprotocol}{方案编号} %<Note: Update prot
20 \newcommand{\fssstudyprotocol}{研究\hspace{0em}\<hspac
21 \newcommand{\fsfirstbodypage}{4} %<Note: Set the fir
22
23 \input{format/preamble.tex} %<Note: No need to updat
24
25 \begin{document}
26
27 % [Title_Toc_Body]
28 \input{format/title_toc_body.tex} %<Note: No need to
29
```

adrg.pdf

C:\Users\zhangshuijiang\Desktop>RG工具>adrg_cn_v1.0>adrg.pdf

分析数据审阅说明

申办方名称
研究<方案编号>

Internal Version 1.0

Ln 102, Col 38 Tab St



Conclusion

- The Reviewer's Guide is a crucial component of data submission to health authorities such as the FDA, with high requirements for formats
- LaTeX offers several potential advantages:
 - Superior Typesetting and automated formatting
 - Consistency
 - Efficiency
- LaTeX's disadvantages:
 - New code language
 - Classic interface
- In summary, while Word may be more intuitive and convenient for many daily tasks, LaTeX provides greater flexibility, precision, and stability when working with long, complex documents in the clinical trial industry



Reference

- LaTeX basic introduction: <https://www.overleaf.com/learn>
- LaTeX package document: <https://texdoc.org/index.html>
- Tables generation online: https://www.tablesgenerator.com/latex_tables
- SDRG Completion Guidelines :
[https://advance.phuse.global/display/WEL/Clinical+Study+Data+Reviewer's+Guide+\(cSDRG\)+Package](https://advance.phuse.global/display/WEL/Clinical+Study+Data+Reviewer's+Guide+(cSDRG)+Package)
- ADRG Completion Guidelines:
[https://advance.phuse.global/display/WEL/Analysis+Data+Reviewer's+Guide+\(ADRG\)+Package](https://advance.phuse.global/display/WEL/Analysis+Data+Reviewer's+Guide+(ADRG)+Package)

Thank You!

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**The Global Healthcare
Data Science Community**

Contact Channels

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✉ office@phuse.global
🌐 phuse.global

Social Media

🐦 [@phusetwitta](https://twitter.com/phusetwitta)
📘 [/phusebook](https://facebook.com/phusebook)
▶ [/phusetube](https://youtube.com/phusetube)
🌐 [/company/phuse](https://linkedin.com/company/phuse)