

Single Day Event

Reporting Packages in R for TLFs

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Agenda

- ☐ Introduction to TLFs
- ☐ POC Workflow
- ☐ POC Features
- ☐ *Flextable and Officer* Package Overview
- ☐ DM and VS Sample Output
- ☐ Lessons Learned
- ☐ Summary

“Are (R) we ready for TLFs?”



Introduction to TLFs

- ❑ Tables, Listings, and Figures (TLFs) are generated as part of reporting requirements within clinical regulatory submissions. Clinical trial data is analyzed and presented as tables and figures in Clinical Study Reports (CSRs). TLFs are also used to answer health authority questions and to support publications based on the clinical trial data.
- ❑ Traditionally, SAS has been used to generate TLFs within Life Sciences for decades as critical component of their clinical study life cycle.
- ❑ Of late, the use of open-source languages such as R has started to build momentum as a lower cost method for development of TLFs.





POC Workflow

Upload File

Select
Variables

Choose
Statistical
Operations

Display
Summary Table

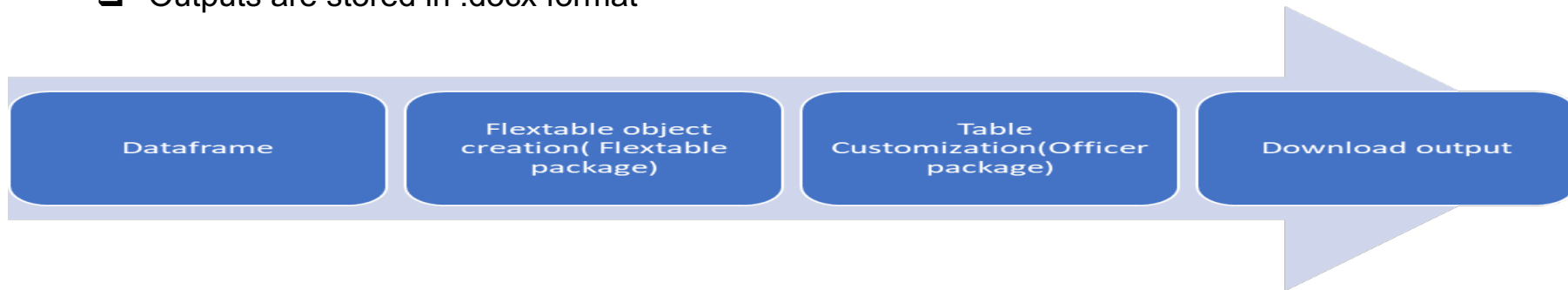
Provide Table
Number, Title
and Footnotes
Dynamically

Download the
Output as .docx
Format



POC Features

- ☐ Input files such as .sas7bdat, .xpt, .csv, .xlsx, .json are accepted
- ☐ Dynamic selection of variables
- ☐ User can provide title, table number, footnotes dynamically
- ☐ User can change the rowlabels and column labels
- ☐ User can give multiple titles and footnotes
- ☐ Outputs are stored in .docx format





Flextable Package Overview

- ❑ Create “pretty” tables for HTML, Adobe PDF, MS Word and PowerPoint documents from R Markdown. Allows user to modify/format the content and create tables.
- ❑ Used for creating “Flextable” object.
- ❑ Along with “Officer package” beautifies the tabular reports.

Reference Functions:

<code>flextable()</code>	[Convert the dataframe in a flextable object]
<code>add_body()</code>	[Add rows in body part]
<code>add_header()</code> / <code>add_footer()</code>	[Add a row of labels in header or footer part]
<code>merge_h ()</code> / <code>merge_v()</code>	[Merge flextable cells horizontally / vertically]



Officer Package Overview

- ❑ Access and manipulate MS Word and PowerPoint documents from R. The package focuses on tabular and graphical reporting from R.
- ❑ Insert data frame, flextable and images to a Word document.
- ❑ The package does not require any installation of Microsoft products to be able to write Microsoft files.

Reference Functions:

<code>read_docx()</code>	[Create a Word document]
<code>body_add_par()</code>	[Add a paragraph of text]
<code>body_add_table()</code>	[Add a data frame]
<code>body_add_flextable()</code>	[Add a flextable object]
<code>print(target = « name.docx »)</code>	[Export the report to Word]



DM Table Sample Output

`tbl This is demographic table`

	ARM=HTT N = 45	ARM=Not Assigned N = 5	ARM=Placebo N = 45	ARM=Screen Failure N = 25	Total N = 120
AGE					
n	45	5	45	25	120
median	30	22	45	48	37.5
min	18	22	18	26	18
mean	39.11	22	42.89	47.8	41.62
<u>sd</u>	22.95	0	16.82	18.71	19.93
SEX					
F	25 (55.56)	5 (100)	30 (66.67)	10 (40)	70 (58.33)
M	20 (44.44)		15 (33.33)	15 (60)	50 (41.67)

This is footnote1

This is footnote2



VS Table Sample Output

VS Table output

This is sample output

Parameter: Weight

Visit	ARM=Placebo N = 2	ARM= High Dose Drug N = 3	ARM= Low Dose Drug N = 6	Count N = 11
baseline				
n		1	1	2
min		76.66	47.17	47.17
mean		76.66	47.17	61.92
sd				20.85
min, max		76.66, 76.66	47.17, 47.17	47.17, 76.66
mean (sd)		76.66 (.)	47.17 (.)	61.92 (20.85)
Week 2				
n		1	1	2
min		74.84	46.27	46.27
mean		74.84	46.27	60.56

VS Table output

This is sample output

Parameter: Weight

Visit	ARM=Placebo N = 2	ARM1 N = 3	ARM= Low Dose Drug N = 6	Count N = 11
baseline				
n		1	1	2
min		76.66	47.17	47.17
mean		76.66	47.17	61.92
sd				20.85
min, max		76.66, 76.66	47.17, 47.17	47.17, 76.66
mean (sd)		76.66 (.)	47.17 (.)	61.92 (20.85)
Week 2				
n		1	1	2
min		74.84	46.27	46.27
mean		74.84	46.27	60.56



Lessons Learned

- ☐ Feasibility check for customizable Table creation using R
- ☐ Explored different packages and identified flextable & officer are suitable packages for table creation.
- ☐ Customizable options for table number, title, footnotes, rowlabels and column labels is feasible.



Summary

POC Status : Completed

In Scope : Table creation using dm and vs files.

Future vision : Table creation for all files.
Listings and Figures creation.

Thank you!

Questions?



**The Global Healthcare
Data Science Community**

Contact Channels

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Social Media

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