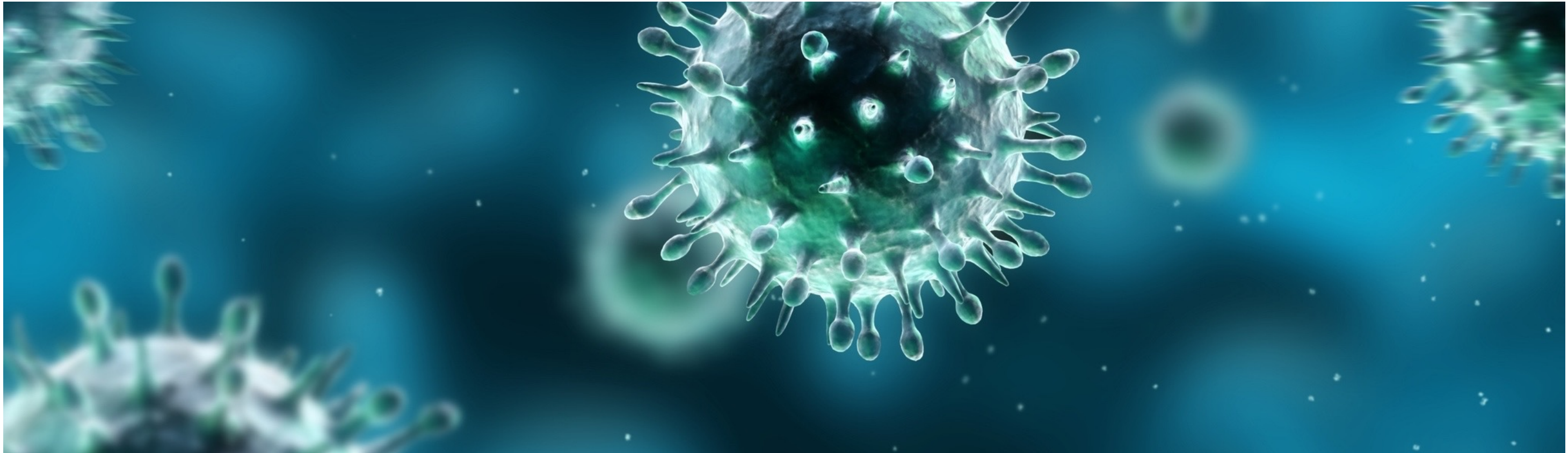




SS02

Combine multiple R outputs into one HTML file with the bookmarks

PHUSE US Connect 2022
Atlanta, Georgia, USA

Eric Zhang
Baoqing Li

H1N1 influenza virus

Author: Eric Zhang

Title: Principal Statistical Programming Lead

Company: Janssen Pharmaceuticals

Address: Spring House, PA, USA

Eric has 26 years experience of the statistical programming in pharmaceutical industry

Author: Baoqing Li

Title: Director, Head of C&SP China

Company: Janssen Pharmaceuticals

Address: Spring House, PA, USA

Baoqing has 23 years experience of the statistical programming in pharmaceutical industry

Agenda

 Generate R tables and listings and figures

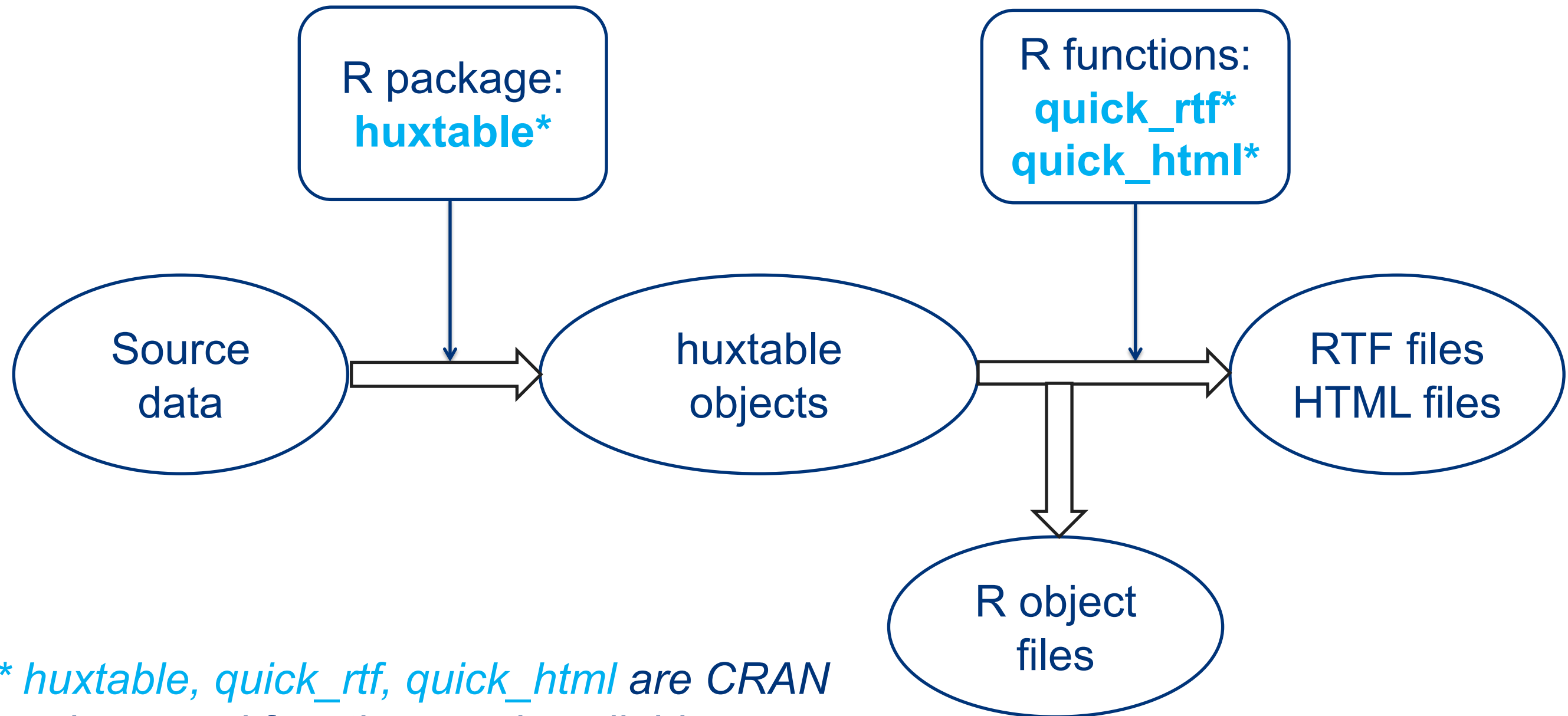
 Combine TLFs into one HTML file with sample

 Combine topline TLFs into one HTML file with sample

 Lessons Learned

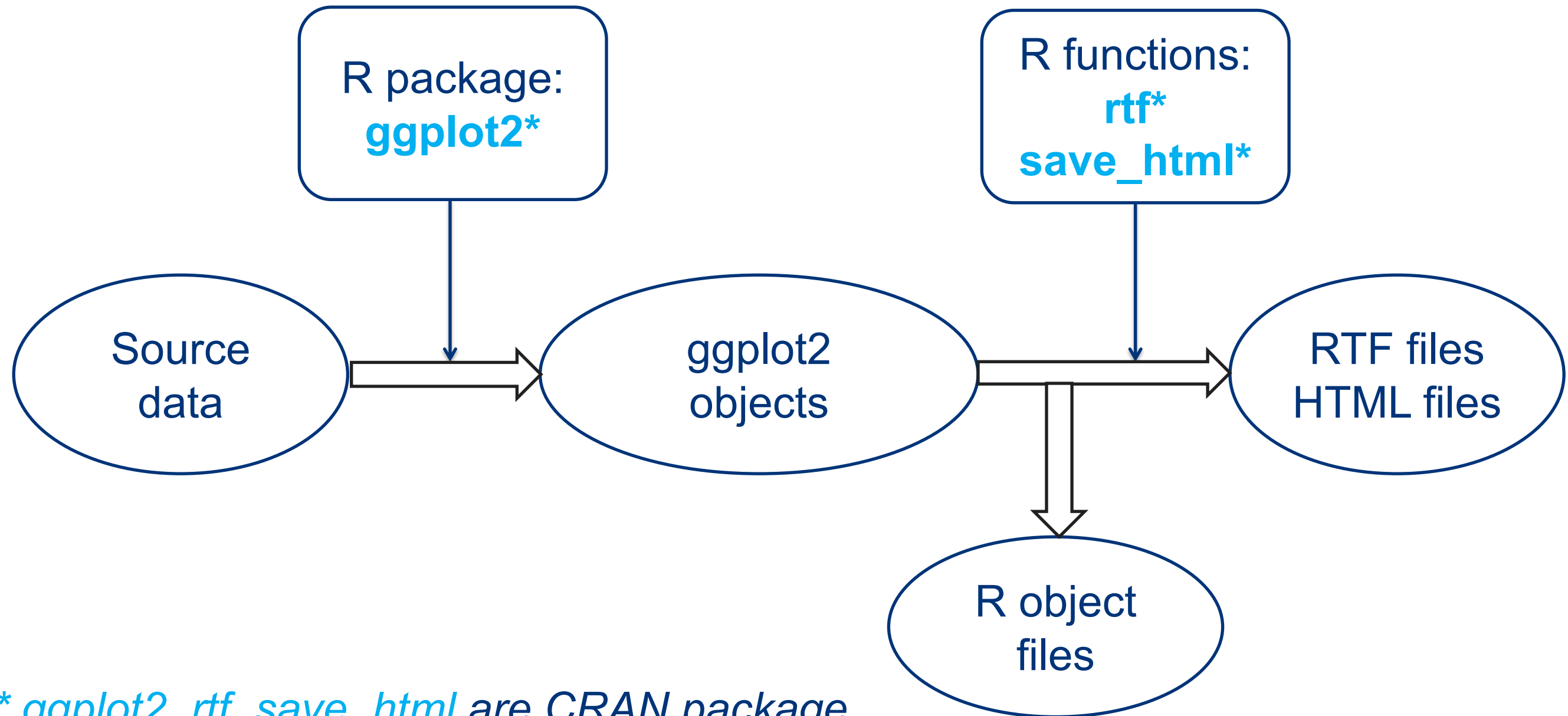
 Q&A

Generate R tables and listings



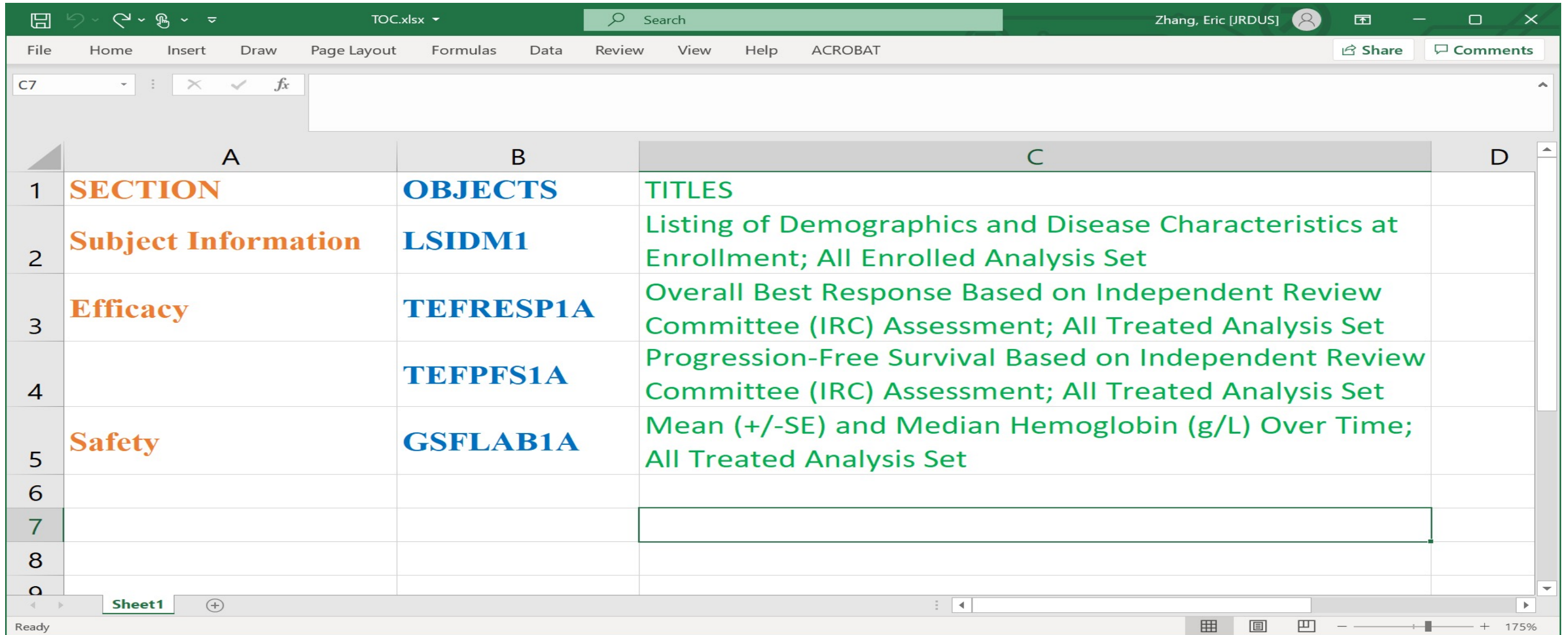
** `huxtable`, `quick_rtf`, `quick_html` are CRAN package and functions and available on the internet*

Generate R figures



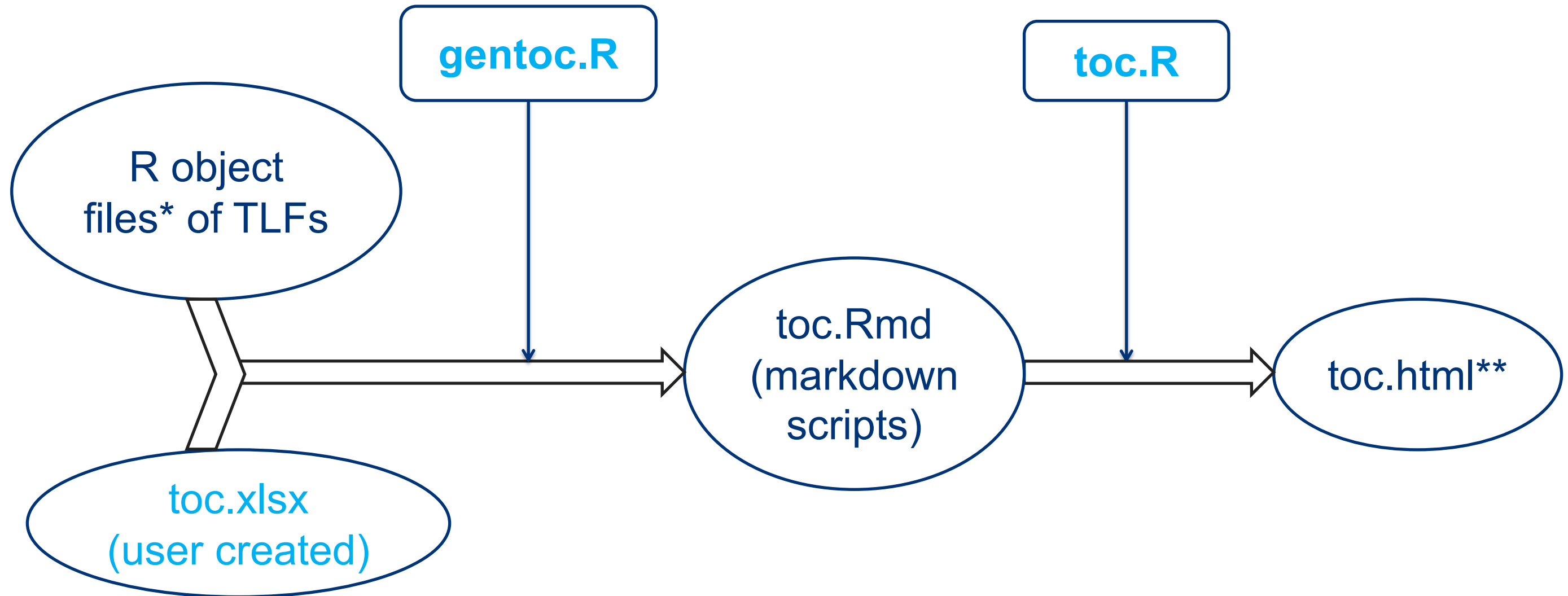
** ggplot2, rtf, save_html are CRAN package and functions and available on the internet*

Sample of toc.xlsx (user created)



	A	B	C	D
1	SECTION	OBJECTS	TITLES	
2	Subject Information	LSIDM1	Listing of Demographics and Disease Characteristics at Enrollment; All Enrolled Analysis Set	
3	Efficacy	TEFRESP1A	Overall Best Response Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set	
4		TEFPFS1A	Progression-Free Survival Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set	
5	Safety	GSFLAB1A	Mean (+/-SE) and Median Hemoglobin (g/L) Over Time; All Treated Analysis Set	
6				
7				
8				
9				

Combine TLFs into one HTML file



* *huxtable* and *ggplot2* objects, ** *markdown* document

Sample of toc.html

1 - Subject Information

2 - Efficacy

2.1 - TEFRESP1A: Overall Best Response Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set

2.2 - TEFPS1A: Progression-Free Survival Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set

3 - Safety

2 - Efficacy

2.1 - TEFRESP1A: Overall Best Response Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set

TEFRESP1A: Overall Best Response Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set

	dummy 1		dummy 2	
	n (%)	95% CI for %	n (%)	95% CI for %
Analysis set: all treated	34		66	
Best response				
Stringent complete response (sCR)	16 (47.1%)	(38.3%, 58.1%)	40 (60.6%)	(46.2%, 70.6%)
Complete response (CR)	8 (23.5%)	(13.3%, 30.6%)	12 (18.2%)	(9.2%, 26.3%)
Very good partial response (VGPR)	5 (14.7%)	(7.2%, 25.4%)	8 (12.1%)	(7.5%, 21.8%)
Partial response (PR)	3 (8.8%)	(4.1%, 13.8%)	3 (4.5%)	(0.9%, 9.4%)
Minimal response (MR)	0	(NE, NE)	0	(NE, NE)
Stable disease (SD)	2 (5.9%)	(2.1%, 8.3%)	0	(NE, NE)
Progressive disease (PD)	0	(NE, NE)	2 (3.0%)	(0.1%, 6.9%)
Not evaluable (NE)	0	(NE, NE)	1 (1.5%)	(0.0%, 5.3%)
Overall response (sCR + CR + VGPR + PR)	32 (94.1%)	(85.1%, 100.0%)	63 (95.5%)	(88.6%, 99.9%)
Clinical benefit (Overall response + MR)	32 (94.1%)	(85.1%, 100.0%)	63 (95.5%)	(88.6%, 99.9%)
VGPR or better (sCR + CR + VGPR)	29 (85.3%)	(72.2%, 99.9%)	60 (91.0%)	(81.8%, 96.7%)
CR or better (sCR + CR)	24 (70.6%)	(58.3%, 86.1%)	52 (76.5%)	(62.3.2%, 90.6%)

Key: CI = confidence interval; NE = not estimable.

Note: Response was assessed by independent review committee (IRC), based on International Myeloma Working Group (IMWG) consensus criteria (2016).

Note: Percentages are calculated with the number of subjects in the all treated analysis set as denominator.

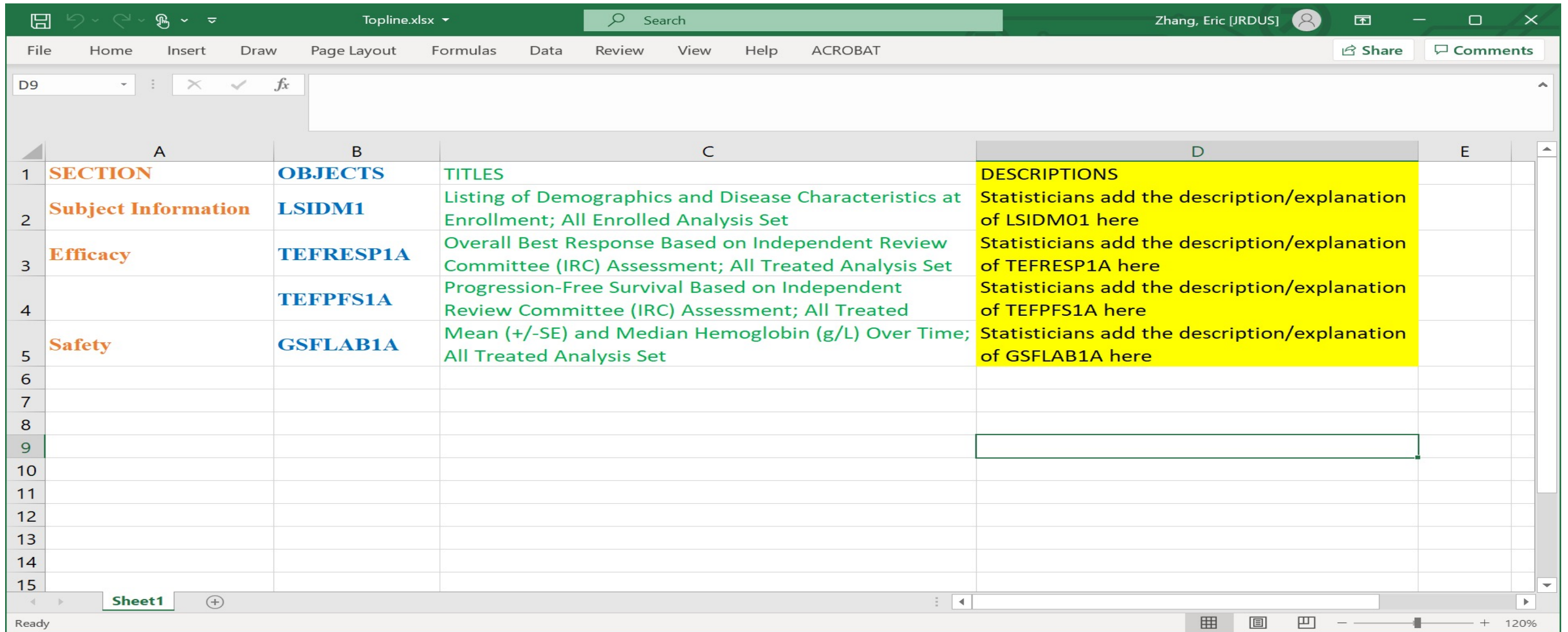
Note: Exact 95% confidence intervals are provided.

[TEFRESP1A] [C:/RStudio/Presentations/PhuseUSConnect2022/Programs/TEFRESP1A.R] 2022-3-13 20:34:55

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Note: the data at toc.html is dummy data

Sample of topline.xlsx (user created)



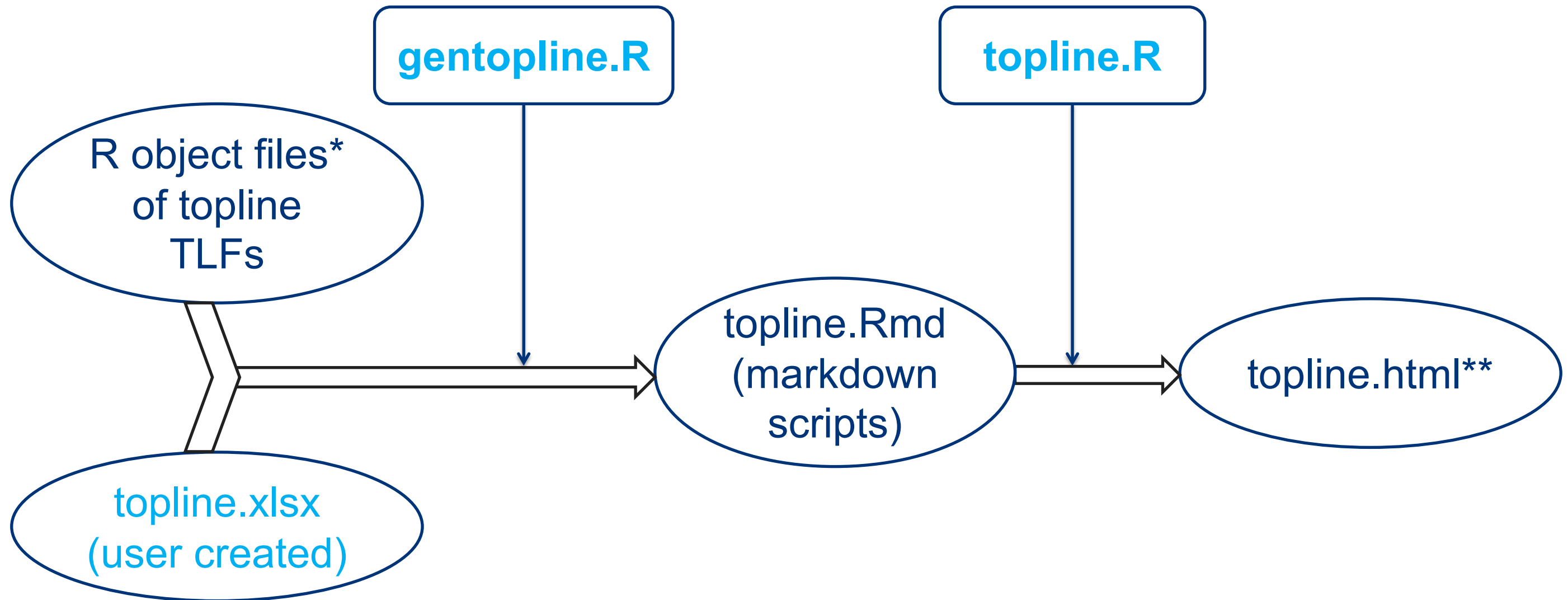
The screenshot shows a Microsoft Excel spreadsheet titled "Topline.xlsx". The spreadsheet has a table with the following structure:

	A	B	C	D	E
1	SECTION	OBJECTS	TITLES	DESCRIPTIONS	
2	Subject Information	LSIDM1	Listing of Demographics and Disease Characteristics at Enrollment; All Enrolled Analysis Set	Statisticians add the description/explanation of LSIDM01 here	
3	Efficacy	TEFRESP1A	Overall Best Response Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set	Statisticians add the description/explanation of TEFRESP1A here	
4		TEFPFS1A	Progression-Free Survival Based on Independent Review Committee (IRC) Assessment; All Treated	Statisticians add the description/explanation of TEFPFS1A here	
5	Safety	GSFLAB1A	Mean (+/-SE) and Median Hemoglobin (g/L) Over Time; All Treated Analysis Set	Statisticians add the description/explanation of GSFLAB1A here	
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					

The DESCRIPTIONS column (D) is highlighted in yellow. The spreadsheet interface includes the ribbon (File, Home, Insert, Draw, Page Layout, Formulas, Data, Review, View, Help, ACROBAT), a search bar, and a status bar at the bottom showing "Ready" and "120%".

Topline are subset of TLFs and statisticians add descriptions

Combine topline TLFs into one HTML file



* *huxtable* and *ggplot2* objects, ** *markdown* document

Sample of topline.html

1 - Subject Information	
2 - Efficacy	
2.1 - TEFRESP1A: Overall Best Response Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set	
2.2 - TEFPFS1A: Progression-Free Survival Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set	
3 - Safety	

2.2 - TEFPFS1A: Progression-Free Survival Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set

TEFPFS1A: Progression-Free Survival Based on Independent Review Committee (IRC) Assessment; All Treated Analysis Set

	dummy 1	dummy 2	dummy 1 + dummy 2
Analysis set: all treated	34	66	100
Progression-free survival			
Number of events (%)	8 (23.5%)	12 (18.2%)	20 (10.0%)
Number of censored (%)	26 (76.5.0%)	54 (81.8%)	80 (80.0%)
Kaplan-Meier estimate (months)			
25% quantile (95% CI)	15.56 (5.87, NE)	18.57 (8.42, NE)	17.12 (7.57, NE)
Median (95% CI)	NE (17.84, NE)	NE (NE, NE)	NE (17.84, NE)
75% quantile (95% CI)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
6-month progression-free survival rate % (95% CI)	90.1 (78.1, 96.2)	83.4 (70.4, 92.8)	86.5 (74.2, 93.8)
9-month progression-free survival rate % (95% CI)	83.2 (67.3, 91.6)	72.8 (61.9, 84.3)	78.3 (68.9, 86.0)
12-month progression-free survival rate % (95% CI)	76.8 (64.4, 88.4)	74.6 (59.5, 82.6)	75.6 (65.0, 83.3)
18-month progression-free survival rate % (95% CI)	58.7 (35.9, 78.9)	NE (NE, NE)	60.7 (38.9, 72.9)

Key: CI = confidence interval; NE = not estimable.

[TEFPFS1A] [C:/RStudio/Presentations/PhuseUSConnect2022/Programs/TEFPFS1A.R] 2022-3-13 20:33:26

Statisticians add the description/explanation of TEFPFS1A here

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3 - Safety

Note: the data at topline.html is dummy data

Lessons Learned

- Many CRAN packages and functions are available to generate TLFs. Sample codes of using these packages and functions are found on the internet
- Learned R markdown scripts to organize TLFs in HTML file
- Learned writing R program to generate the markdown scripts
- Learned organizing TLFs with the desired positions and orders and/or descriptions in HTML file via excel file
- Learned HTML codes to add descriptions of topline TLFs in HTML file
- The codes and descriptions of codes are in the paper. We may consolidate two programs, which generate R markdown scripts, to one program

Q&A



