

Single Day Event

From SAS to R in TFL Generation
for Regulatory Submissions

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Agenda

- Why Switch to R?
- Goals for Success
- Current Process
- R Transition Strategy
- Multilingual Submissions
- Summary and QA



Why Switch to R?





Goals for Success



- Results 100% consistency
- Formats 100% consistency



- Process Automation
- R's Core Strengths

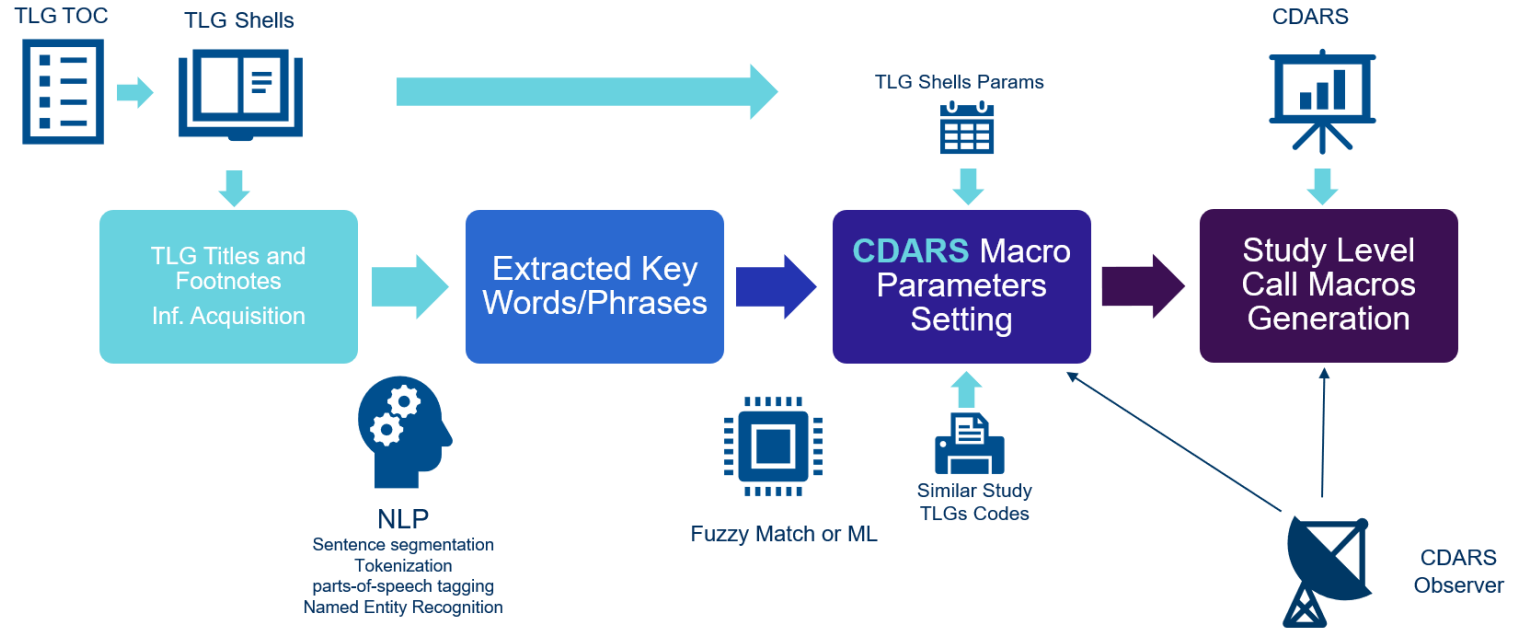


- Reduce learning curve
- Same process, naming



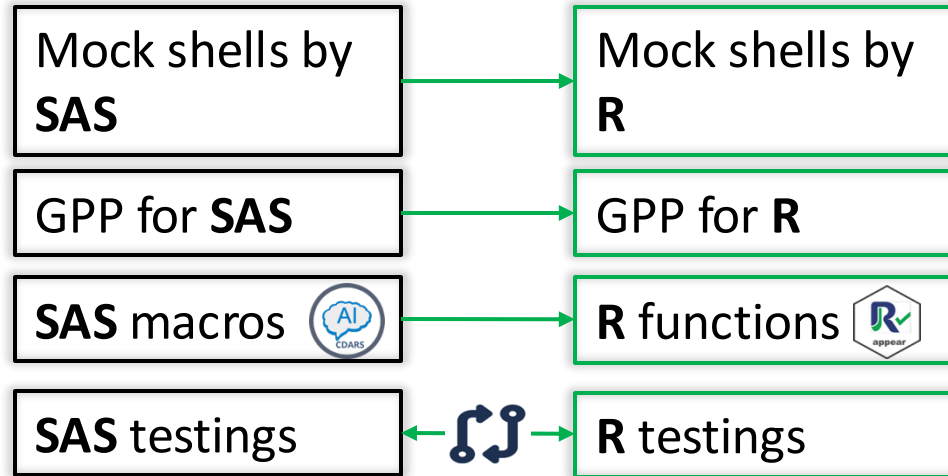
- Keep up with evolving regulatory standards

Current Process



Clinical **D**ata **A**nalysis and **R**eporting **S**ystem (**CDARS**) is a One-click SAS® Application that produces standard statistical tables and listings based on Dizal's standard Tables, Graphs, and Listings.

R Transition Strategy



Abbreviation: GPP = Good Programming Practice



GPP for R

- **Project Level**
 - renv for package version control
 - Unified folder structures & utility functions
- **Study Level**
 - One script per dataset/TLG (dynamic, no hard-coding)
 - Explicit package loading: `library()` or `pkg::fun()`
- **Program Level**
 - Snake_case naming (e.g., `day_one`)
 - Structured scripts (header → packages → logic)
 - Vectorization over loops (10-100x faster)
- **Code Quality**
 - Style: 2-space indentation, ≤80 char lines
 - Debugging: `browser()`, `tryCatch()`, breakpoints
 - Static Analysis: `lintr` package for automated checks
 - Documentation: YAML headers + Roxygen2 for functions

Package selection criteria:

- Ensured quality
- Minimal dependency
- High versatility



Issue 1, Missing SimSun Font

github.com/Merck/r2rtf/issues/256

Closed Add Font "SimSun" for generating Chinese Version Report #256

We also encountered this issue. When outputting Chinese text, because the 10 fonts included in `r2rtf:::font_type()` do not contain SimSun, we had to **manually modify** the generated RTF file:

1. Add `{\f10\fn11\fcharset134\fpq2 SimSun;}` to the `\fonttbl` section;
2. Replace all font tags `\f0` with `\f10\f0`.

This ensures that Chinese characters are displayed in SimSun while English text remains in Times New Roman, meeting CDE requirements.

If the `r2rtf` package could be modified at the source level to set this as the default, it would directly address the Chinese submission requirements!

@elong0527 Please find the CDE requirements (Page 24, font request):

<https://www.nmpa.gov.cn/directory/web/nmpa/images/1632971756191079756.pdf>

Here is my code, which is used for post-processing by adding the **SimSun** font.

```
library(r2rtf)

# Create Data Frame (Chinese)
df <- data.frame(ID=1:10, ARM=rep(c("组A","组B"),5), SEX=c(rep("男",4),rep("女",6)))

# Add宋体
addSimSun <- function(x){
  x[[1]] <-
    sub("(\\f9\\ftech\\fcharset161\\fpq2 Symbol;)",
        "\\f9\\ftech\\fcharset161\\fpq2 Symbol;\\n(\\f10\\fn11\\fcharset134\\fpq2 SimSun;)", x[[1]], fixed=TRUE)
  x[[2]] <- gsub("\\f0 ", "\\f10\\f0 ", x[[2]], fixed=TRUE)
  x
}

# Output to RTF
df |>
  rtf_title("中文标题") |>
  rtf_footnote("中文注释") |>
  rtf_colheader("第1列|第2列|第3列") |>
  rtf_body() |>
  rtf_encode() |>
  lapply(utf8ToRtf) |>
  addSimSun() |>
  write_rtf("test.rtf")
```



Issue 2, Different Layouts

Adverse Event Count by Treatment Group

Adverse Events	Placebo	Xanomeline High Dose	Xanomeline Low Dose
ABDOMINAL PAIN	1	2	3
AGITATION	2	1	2
ALOPECIA	1	0	0
ANXIETY	2	0	4
APPLICATION SITE DERMATITIS	9	12	15
APPLICATION SITE ERYTHEMA	3	23	20
[datasource: adam-adae]			

Default Layout

R-FUNCTIONS-DEV-AR_REPORTS

Page 1 of 3

Table 14.1.2.1
Summary of Demographic and baseline characteristics
Safety Analysis Set

	Level 1 Span Header					
	Level 2 Span Header 1			Level 2 Span Header 2		
	Arm 1 (N = xx) n (%)	Arm 2 (N = xx) n (%)	Arm 3 (N = xx) n (%)	Arm 4 (N = xx) n (%)	Arm 5 (N = xx) n (%)	Arm 6 (N = xx) n (%)
Age (Years)						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Sex						
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race						
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity						
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Height (cm)						

Please refer to last page for complete footnotes.

Dizal Appendix



Different Layouts

Table 14.1.2.2: Summary of Demographic and baseline characteristics (Safety Analysis Set)

	Level 1 Span Header					
	Level 2 Span Header 1			Level 2 Span Header 2		
	Arm 1 (N = xx) n (%)	Arm 2 (N = xx) n (%)	Arm 3 (N = xx) n (%)	Arm 4 (N = xx) n (%)	Arm 5 (N = xx) n (%)	Arm 6 (N = xx) n (%)
Age (Years)						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Sex						
Male	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Female	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race						
Asian	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity						
Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic or Latino	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Reported	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Height (cm)						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
Weight (kg)						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
BMI (kg/m ²)						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min, Max	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx	xx, xx
ECOG Performance Status						
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

In-text

Table 14.3.2.2: Example of stack tables (Safety Analysis Set)

Treatment Group	N	Baseline		Average Change from Baseline	
		Mean	SD	LS Mean	95% CI for LS Mean
Drug A	113	0.38	0.32	-0.04	-0.08, 0.00
Drug B	114	0.38	0.28	-0.04	-0.08, 0.00
Placebo	115	0.38	0.31	-0.04	-0.08, 0.00
Between-treatment Comparisons from ANOVA Model					
Comparison		Difference in LS Means		95% CI for Difference	p-value
Drug A vs. Placebo		-0.08		(-0.14, -0.02)	<0.001
Drug B vs. Placebo		-0.08		(-0.14, -0.03)	0.412
Drug A vs. Drug B		0.00		(-0.05, -0.06)	0.999

Source: ADL, ADAE

Data extraction: 16OCT2019, Data cut-off: 16OCT2019

/ar-dev/r-functions-dev/rd2reports/round01-30may2025/pgmanal/intexts/t-stack-1 R 05Nov2025 10:13 t-stack-1.rtf

watermark

- Option A: Configure function parameters
- Option B: Modify the RTF code
- Option C: Refactor the function





Macros to Functions

macro	function	description
m_ar_ae_cat_adr	an_ae_cat_adr	Calculate AE summary table by category for Adverse Drug Reactions (ADRs)
m_ar_ae_cat_adr_duration	an_ae_cat_adr_duration	Calculate AE summary table by category for Adverse Drug Reactions (ADRs) with median duration
m_ar_ae_eair	an_ae_eair	Exposure-Adjusted Incidence Rate of TEAE by Preferred Term
m_ar_ae_eair_event	an_ae_eair_event	Exposure-Adjusted Incidence Rate of TEAE by Preferred Term and by event
m_ar_ae_grp_cutoff	an_ae_grp_cutoff	Calculate summary table of AE by System Organ Class, Preferred Term, Worst Grade
m_ar_ae_lst	an_ae_lst	Develop AE listing
m_ar_ae_socpt	an_ae_socpt	Calculate summary table of AE by System Organ Class, Preferred Term, and Worst Grade
m_ar_ae_socpt_adr	an_ae_socpt_adr	Calculate summary table of AE for Adverse Drug Reactions (ADRs)
m_ar_ae_sum	an_ae_sum	Calculate AE summary table
m_ar_bor	an_bor	Develop summary of tumor response table
m_ar_bor_cnc	an_bor_cnc	Develop summary of tumor response table presenting both confirmed and not confirmed parts
m_ar_bor_compare	an_bor_compare	Develop summary of tumor response table containing group comparison
m_ar_bor_subgrp	an_bor_subgrp	Develop table for subgroup analysis of tumor response
m_ar_boxplots	an_boxplots	Generate box Plot
m_ar_cat_cont	an_cat_cont	Create table like demographic and disease history
m_ar_cm_commed	an_cm_commed	Calculate summary table of CM by ATC Level 2 Term, ATC Level 4 Term, Preferred Term
m_ar_comp_chg	an_comp_chg	Calculate summary table of lab, vital sign, ecg and ecog assessment
m_ar_count	an_count	Calculate Frequency and Percentage
m_ar_count_stat	an_count_stat	Calculate Frequency and Percentage
m_ar_death	an_death	Create summary of death table
m_ar_dili	an_dili	Create summary of Potentially Drug-Induced Liver Injury
m_ar_dili_edish_quadrant	an_dili_edish_quadrant	Create Summary of Maximum Post Baseline ALT or AST and Maximum Post Baseline Total Bilirubin
m_ar_dili_edishplots	an_dili_edishplots	Generate eDISH (Evaluation of Drug-Induced Serious Hepatotoxicity) plot
m_ar_dili_hys	an_dili_hys	Create summary of Potential Hys Law
m_ar_dili_shift	an_dili_shift	Calculate Shift Table of Aminotranferase Based on the Worst Value Post Baseline
m_ar_ds	an_ds	Create disposition table
m_ar_dv	an_dv	Calculate summary table of Protocol Deviations
m_ar_ecg_abn	an_ecg_abn	Create Summary table of Participants with Abnormal ECG Measurements.
m_ar_ecg_shift	an_ecg_shift	Calculate shift table for ECG normal range
m_ar_ecog_cat	an_ecog_cat	Develop frequency summary of ecog performance status
m_ar_ecog_shift	an_ecog_shift	Calculate shift table for ecog assessment
m_ar_forestplots	an_forestplots	Generate Forest Plot from Well-Processed Data
m_ar_grade_incr_cat	an_grade_incr_cat	Calculate table for CTCAE Grade Shift of LB assessment
m_ar_grade_increased	an_grade_increased	Calculate table for CTCAE Grade Shift of LB assessment by visit
m_ar_grade_shift	an_grade_shift	Calculate shift table for CTCAE Grade of LB/VS assessment
m_ar_greplay	an_greplay	Generate bar chart
m_ar_kmplots	an_kmplots	Generate KM Plot with CI/SE bar as well as Statistical Summary table and counts tables
m_ar_lb_grade3	an_lb_grade3	Calculate Summary of Laboratory Abnormalities with CTCAE Grade 23
m_ar_lb_worsen_grd	an_lb_worsen_grd	Calculate Summary of Laboratory Abnormalities Worsening from Baseline by CTCAE Grade
m_ar_lbplots_inv	an_lbplots_inv	Generate plot for Laboratory assessment together with exposure and/or concomitant medication
m_ar_lftplots	an_lftplots	Generate Liver Function Test Plot
m_ar_lineplots	an_lineplots	Generate line plot showing estimate, lower and higher confidence limit
m_ar_lineplots_fulldata	an_lineplots_fulldata	Calculate estimate, lower and higher confidence limit as well as show them in line plot
m_ar_lineplots_inv	an_lineplots_inv	Generate individual line plot
m_ar_mean	an_mean	Calculate Summary Statistics: Min, Max, Median, SD, Min, Max, Q1, Q3



Macros to Functions: Parameters

function	parameter	type	len_min	len_max	toupper	default	description
ar_reports	input_dataset	data.frame	1	1			(required) Input dataset for creation of TFL
ar_reports	rpt_vars	character	1	Inf	Y	intersect(names(input_dataset), paste0("COL", 1:99))	(required) Specify variables used in column statement, separated by space or [
ar_reports	rpt_headers	character, list	ncol	ncol		attr(input_dataset, "colheader")	(required) Specify headers for columns, separate by . Each level of headers is enclosed within [] Example: [Level 1 Span Header ^^^^^^] [Level 1 Span Header 1 ^^^ Level 2 Span Header 2 ^^^] [Response Arm1_1_1000(N) Arm 2_1_1000(N) Arm3_1_1000(N) Arm4_1_1000(N) Arm5_1_1000(N) Arm6_1_1000(N)]
ar_reports	column_width	numeric	ncol	ncol		c(3, rep(1, length(rpt_vars) - 1))	(required) Specify width for columns that need to be specially specified. Separate by space
ar_reports	column_alignment	character	0	Inf		c("l", rep("c", length(rpt_vars) - 1))	(required) L - Left aligned; C - Center aligned; R - Right aligned. Example: L C C C C
ar_reports	header_alignment	character	1	1		column_alignment	(optional) L - Left aligned; C - Center aligned; R - Right aligned. Default is the same as value of column_alignment.
ar_reports	sort_vars	character	0	Inf	Y	NULL	(optional) Specify variables used to sort tfl according to their order in input dataset.
ar_reports	noprnt_vars	character	0	Inf	Y	NA	(optional) Specify variables in column statement that will not be displayed in tfl.
ar_reports	group_vars	character	0	Inf	Y	NULL	(optional) Specify group variable, separated by space. Example: coll
ar_reports	by_vars	character	0	Inf	Y	NULL	(optional) Specify variable list in by statement example: age agen sex sexn title4 justify = left "#byval(age)"; titles justify = left "#byval(sex)";
ar_reports	line_brk_vars	character	0	Inf	Y	NULL	(optional) A group variable like AESOC; used to insert a blank row after a whole group example: aesoc - will place a blank row after each aesoc group example: aesoc aesocn will place a blank row and a row with value of aesoc after each aesoc group.
ar_reports	page_brk_var	character	0	Inf	Y	NULL	(optional) Specify variable in break statement for PAGE break purpose
ar_reports	line_num_per_page	numeric	1	1		ifelse(destination == "I", Inf, ifelse(toupper(layout_orientation) == "LANDSCAPE", 21, 34))	(Optional) How many lines of data to be displayed in one page. Default will be calculated automatically from layout orientation, titles, footnotes and table headers. Maximum value is 21 for landscape and 34 for portrait. line_num_per_page is valid only when destination is A.
ar_reports	watermark	character	0	1		NULL	(optional) Water Mark like Final or Dry Run. Default is missing. This is only available for intext TFL.
ar_reports	outfile_name	character	1	1			(required) Outfile_name is for output RTF file name and used to extract title and footnote from title and footnote excel file. The extension .rtf is not needed. Follow naming convention listed in section 6.2 of DZ-WI-SP-004.01. '-i' at end of outfile name will be added automatically for intext TFL. Example: T-ae-overview-saf or l-dm-demog-itt or f-vs-means-saf
ar_reports	title_footnote_template	data.frame	1	1		get0("tlaft")	(optional) Title and footnote excel file or sas datasets following global template. Example: &protpath/metadata/system/m_titles_rpt.xlsx or fptmty(m_titles_rpt.xlsx) or lptmty.tlaft
ar_reports	tfl_title	character	0	1		NULL	(optional) TFL title when title is not from excel file. There are 3 pieces of information separated by list piece: TFL number. 2nd piece: TFL title. 3rd piece: TFL population. Example: Table 14.3.2.2 Overall Summary of Treatment-Emergent Adverse Events Safety Analysis Set
ar_reports	tfl_footnote	character	0	1		NULL	(optional) TFL footnotes concatenated with " " when footnote is not from excel file. Example: Abbreviations: DLT = dose limiting toxicity; SAE = serious adverse event; TEAE = treatment adverse event. All percentages are based on N.
ar_reports	footnote_on_last_page	logical	1	1		ifelse(destination == "A", TRUE, FALSE)	(optional) Display extremely long footnote on last page (Y/N)? Default is N.
ar_reports	output_path	character	1	1		u_output_path(outfile_name, destination)	(optional) Path where output rtf file to be placed, default is fprnt when destination is I, fprtb when destination is A and index(outfile_name, "T-"), fprlst when destination is A and index(outfile_name, "L-")
ar_reports	output_dtl1b	character	1	1		NA	(optional) Libname for output TFL dataset, default is lptint when destination is I, lptbt when destination is A and index(outfile_name, "T-"), lptlst when destination is A and index(outfile_name, "L-")
ar_reports	output_dataset	character	1	1		NA	(optional) Name of sas dataset for the output rtf. Default is derived from outfile_name and destination.
ar_reports	stack	numeric	1	1		0	(optional) Allow stacking several SAS datasets (could be in different structures) into one RTF table. Valid values include integers between 0 and 100. 0 - No stack (default). 1 - First/top table. 100 - last/bottom table. Other integers - middle tables
ar_reports	layout_orientation	character	1	1	Y	ifelse(destination == "A", "LANDSCAPE", "PORTRAIT")	(optional) Orientation of layout. default is Portrait/P when destination is I and Landscape/L when destination is A
ar_reports	font_size	numeric	1	1		ifelse(destination == "A", 10, 11)	(optional) Font size of table header and table text. Default is 10 for appendix and 11 for intext. Valid values include 9, 10, 11.
ar_reports	language	character	1	1	Y	get0("language", "EN")	(optional) Language used in TFL. Default is en. Valid values include en (English) and zh (Chinese)
ar_reports	destination	character	1	1	Y	ifelse(grepl("-i \$", outfile_name), "I", "A")	(optional) i - intext TFL; a - appendix



Macros to Functions: Testings

function	parameter	type	value_sas	value_r
ar_ae_sum	input_dataset	data.frame	lptad.adae	adae
ar_ae_sum	input_dataset_where	expression	SAFFL = 'Y'	"SAFFL == 'Y'"
ar_ae_sum	trt_var	character	TRTA TRTAN	"TRTA TRTAN"
ar_ae_sum	aetoxgr_var	character	ATOXGR	"ATOXGR"
ar_ae_sum	aesdth_var	character	AESDTH	"AESDTH"
ar_ae_sum	aerel_vars	character	AREL	"AREL"
ar_ae_sum	aerel_text	character		NULL
ar_ae_sum	aeacn_vars	character	AEACN	"AEACN"
ar_ae_sum	aesi_yn	logical	Y	TRUE
ar_ae_sum	dosdelay_yn	logical	N	FALSE
ar_ae_sum	population_dataset	data.frame	lptad.adsl	adsl
ar_ae_sum	population_dataset_where	expression	SAFFL = 'Y'	"SAFFL == 'Y'"
ar_ae_sum	therapy_var	character	TRT01A TRT01AN	"TRT01A TRT01AN"
ar_ae_sum	display_total	logical	N	FALSE
ar_ae_sum	display_trt	list	[0 Placebo][54 Xanomeline Low Dose][81 Xanomeline High Dose][54,81 Xanomeline Total]	list("levels" = list(0, 54, 81, c(54, 81)), "labels" = c("Placebo", "Xanomeline\\line Low Dose", "Xanomeline\\line High Dose", "Xanomeline\\line Total"))
ar_ae_sum	grp_var	character	SEX	"SEX"
ar_ae_sum	display_grp	list	[F Female][M Male][F, M Total]	list("levels" = list("F", "M", c("F", "M")), "labels" = c("Female", "Male", "Total"))
ar_ae_sum	bign_type	character	TRT	"TRT"
ar_ae_sum	report_yn	logical	Y	TRUE
ar_ae_sum	page_vars	character		NULL
ar_ae_sum	rpt_span_headers	character		NA
ar_ae_sum	column_width	named list		NULL
ar_ae_sum	line_num_per_page	numeric		NULL
ar_ae_sum	outfile_name	character	t-ae-sum	"t-ae-sum"
ar_ae_sum	title_footnote_template	character		NULL
ar_ae_sum	tfl_title	character	%nrbquote(Overall Summary of TEAE Safety Analysis Set)	"Overall Summary of TEAE\\line Safety Analysis Set"
ar_ae_sum	tfl_footnote	character	%nrbquote(Source: ADSL, ADAE Data Extraction: 16Oct2025, Data Cut-off: 16Oct2025.)	"Source: ADSL, ADAE\\line Data Extraction: 16Oct2025, Data Cut-off: 16Oct2025."



Testings: SAS & R

```
%m_ar_ae_sum(  
  input_dataset      = lptad.adae,  
  trt_var            = TRTA|TRTAN,  
  aetoxgr_var        = ATOXGR,  
  aesdth_var         = AESDTH,  
  aere1_vars         = AREL,  
  aere1_text         = Drug,  
  aeacn_vars         = AEACN,  
  aesi_yn            = Y,  
  dosdelay_yn        = N,  
  population_dataset = lptad.adsl,  
  therapy_var        = ,  
  display_total      = N,  
  display_trt        = [0|Placebo][54|Xanomeline Low Dose][81|Xanomeline High Dose][54,  
  grp_var            = SEX,  
  display_grp        = [F|Female][M|Male][F, M|Total],  
  bign_type          = TRT,  
  outfile_name       = t-ae-sum,  
  tfl_title          = %nrbrquote(Overall Summary of TEAE|Safety Analysis Set),  
  tfl_footnote       = %nrbrquote(Source: ADSL, ADAE|Data Extraction: 16Oct2025.)  
)
```

```
ar_ae_sum(  
  input_dataset = adae,  
  trt_var       = c("TRTA", "TRTAN"),  
  aetoxgr_var   = "ATOXGR",  
  aesdth_var    = "AESDTH",  
  aere1_vars    = "AREL",  
  aere1_text    = "Drug",  
  aeacn_vars    = "AEACN",  
  aesi_yn       = TRUE,  
  dosdelay_yn   = FALSE,  
  therapy_var   = NULL,  
  display_total = FALSE,  
  display_trt   = list("levels" = list(0, 54, 81, c(54, 81)),  
                       "labels" = c("Placebo",  
                                     "Xanomeline\\line Low Dose",  
                                     "Xanomeline\\line High Dose",  
                                     "Xanomeline\\line Total")),  
  grp_var       = "SEX",  
  display_grp   = list("levels" = list("F", "M", c("F", "M")),  
                       "labels" = c("Female", "Male", "Total")),  
  bign_type     = "TRT",  
  outfile_name  = "t-ae-sum",  
  tfl_title     = "Overall Summary of TEAE\\line Safety Analysis Set",  
  tfl_footnote  = "Source: ADSL, ADAE\\line Data Extraction: 16Oct2025."  
)
```



Multilingual Submissions

Option A: Two Function Sets



Option B: Unicode Conversion



Option C: Special Code Wrapping for Conditional Removal





```
footnote <-  
  paste0(  
    "\\uc1\\u25968?\\uc1\\u25454?\\uc1\\u26469?\\uc1\\u28304?\\uc1\\u-230?",  
    gsub(",", "\\uc1\\u-244?", title_footnote_template$Source_Reference),  
    "\\line  
\\uc1\\u25968?\\uc1\\u25454?\\uc1\\u25277?\\uc1\\u21462?\\uc1\\u26085?\\uc1\\u26399  
?\\uc1\\u-230?",  
    ifelse(extract_date == "DDMMMYYYY", "YYYY-MM-DD", format(as.Date(extract_date,  
format = "%d%b%Y"), "%Y-%m-%d")),  
    "\\uc1\\u-244?\\uc1\\u25968?\\uc1\\u25454?\\uc1\\u25130?\\uc1\\u-  
32269?\\uc1\\u26085?\\uc1\\u26399?\\uc1\\u-230?",  
    ifelse(cutoff_date == "DDMMMYYYY", "YYYY-MM-DD", format(as.Date(cutoff_date,  
format = "%d%b%Y"), "%Y-%m-%d")),  
    "\\line ",  
    footnote  
  )
```



Option C: Special Code Wrapping for Conditional Removal



```
# EN -> ZH Translation Start
if (language == "ZH") {
  extract_date <- ifelse(extract_date == "DDMMMYYYY", "YYYY-MM-DD",
format(as.Date(extract_date, format = "%d%b%Y"), "%Y-%m-%d"))
  cutoff_date <- ifelse(cutoff_date == "DDMMMYYYY", "YYYY-MM-DD",
format(as.Date(cutoff_date, format = "%d%b%Y"), "%Y-%m-%d"))
  word <- c(
    "数据来源:", "数据抽取日期:", ", 数据截至日期:", "\\line ", "没有符合所选
条件的数据", "请至最后一页查阅完整脚注.", " \\cell \\qr 第\\chpgn 页, 共
{\\field{\\*\\fldinst NUMPAGES}}页\\cell\\row",
    "表", "列表", "图"
  )
}
# EN -> ZH Translation End
```



Beyond a Language Change

By mapping SAS macros to R functions, we have successfully:

- Leveraged the company's existing asset library and metadata
- Capitalized on the team's collective expertise
- Ensured the reliability of outputs
- Established a highly efficient testing and validation mechanism

Built a bridge from our trusted past to a future of possibilities.



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