

# Creating Clinical Tables in R with rtables Package

Yumi Nishimoto  
Tomoyuki Namai

**CHUGAI PHARMACEUTICAL CO., LTD.**

17 November 2023

# Disclaimer



**The views and opinions expressed in this presentation are those of the speakers and do not reflect opinions of any other person or organization.**

# Agenda

01

**Overview**

02

**Basics of rtables**

03

**Examples**

04

**Using tern**

# Agenda

01

**Overview**

02

Basics of rtables

03

Examples

04

Using tern

# Clinical reporting packages listed on pharmaverse website

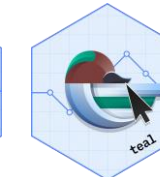
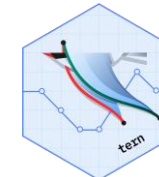
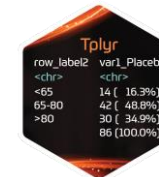
CRF

SDTM

ADaM

TLGs

eSub



# Clinical reporting packages listed on pharmaverse website



# rtables

- R package developed by Roche.
- Open source (Apache License, Version 2.0)
- Provides a framework to create, tabulate and output tables in R.
- table rendering (ASCII, HTML, etc.) is separate from the data model.
- Always has access to the non-rounded/non-formatted numbers.



# Agenda

01

Overview

02

**Basics of rtables**

03

Examples

04

Using tern



# Program structure

```
library(rtables)
```

Table layout

```
lyt <- basic_table(title = "Title", main_footer = "Footnotes.") %>%  
  split_cols_by("ARM") %>%  
  split_rows_by("SEX") %>%  
  analyze("AGE", afun = a_summary)
```

```
tbl <- build_table(lyt, adsl)
```

Building table object

```
export_as_txt(tbl, "table.txt", page_type = "a4")
```

Export

# Layout

```
lyt <- basic_table(title = "Title", main_footer = "Footnotes.") %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)
```

Title

	A: Drug X	B: Placebo	C: Combination
-----			
F			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
M			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0
-----			

Footnotes.

# Layout

```
lyt <- basic_table(title = "Title", main_footer = "Footnotes.") %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)
```

Title			
	A: Drug X	B: Placebo	C: Combination
F			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
M			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0
Footnotes.			

# Layout

```
lyt <- basic_table(title = "Title", main_footer = "Footnotes.") %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)
```

Title			
	A: Drug X	B: Placebo	C: Combination
F			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
M			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

Footnotes.

# Layout

```
lyt <- basic_table(title = "Title", main_footer = "Footnotes.") %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)
```

Title

-----

	A: Drug X	B: Placebo	C: Combination
-----			
<b>F</b>			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
<b>M</b>			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

-----

Footnotes.

# Layout

```
lyt <- basic_table(title = "Title", main_footer = "Footnotes.") %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)
```

Title

	A: Drug X	B: Placebo	C: Combination
F			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
M			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

Footnotes.

# Layout

```
lyt <- basic_table(title = "Title", main_footer = "Footnotes.") %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)
```

## Analysis function

Title

	A: Drug X	B: Placebo	C: Combination
F			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
M			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

Footnotes.

# Analysis function

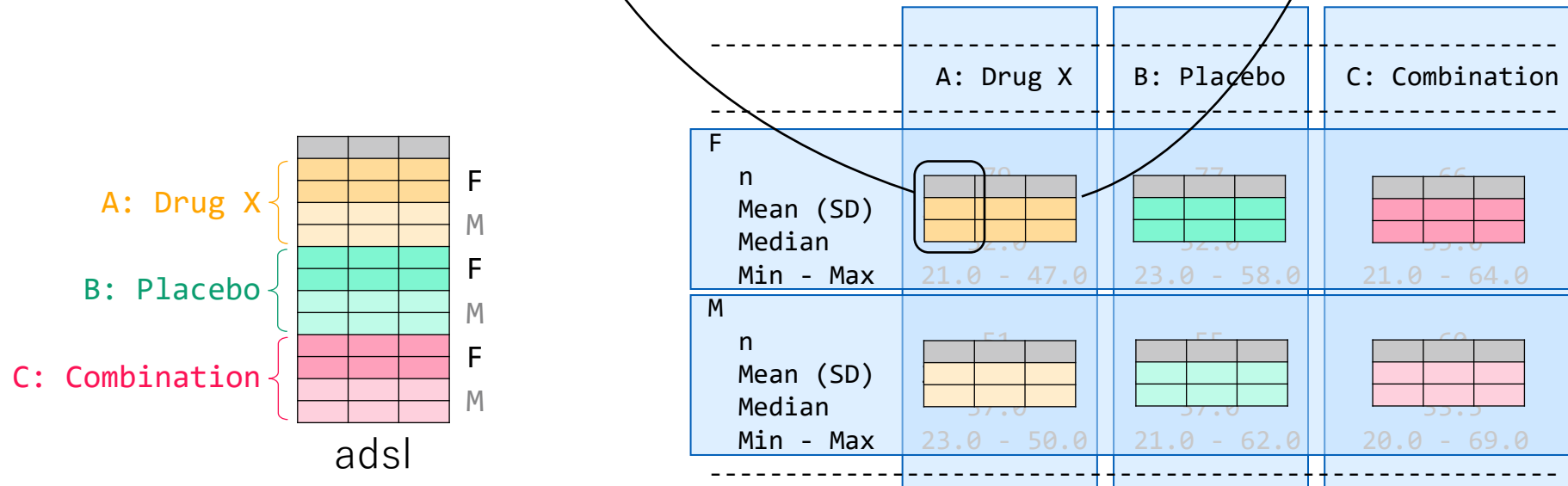
```
a_summary <- function(x) {
  ...
}
```

or

```
a_summary <- function(df) {
  ...
}
```

receive a column (variable)

receive a data frame





# Analysis function

```

a_summary <- function(x) {
  in_rows(
    n = rcell(
      sum(!is.na(x)), format = "xx"
    ),
    mean_sd = rcell(
      c(mean(x), sd(x)), format = "xx.x (xx.x)"
    ),
    median = rcell(
      median(x), format = "xx.x"
    ),
    min_max = rcell(
      range(x), format = "xx.x - xx.x"
    ),
    .labels = c("n", "Mean (SD)", "Median", "Min - Max")
  )
}

```

```

lyt <- basic_table() %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)

```

	A: Drug X	B: Placebo	C: Combination
F			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
M			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

# Analysis function

```

a_summary <- function(x) {
  in_rows(
    n = rcell(
      sum(!is.na(x)), format = "xx"
    ),
    mean_sd = rcell(
      c(mean(x), sd(x)), format = "xx.x (xx.x)"
    ),
    median = rcell(
      median(x), format = "xx.x"
    ),
    min_max = rcell(
      range(x), format = "xx.x - xx.x"
    ),
    .labels = c("n", "Mean (SD)", "Median", "Min - Max")
  )
}

```

```

lyt <- basic_table() %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)

```

	A: Drug X	B: Placebo	C: Combination
F			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
M			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

# Analysis function

```

a_summary <- function(x) {
  in_rows(
    n = rcell(
      sum(!is.na(x)), format = "xx"
    ),
    mean_sd = rcell(
      c(mean(x), sd(x)), format = "xx.x (xx.x)"
    ),
    median = rcell(
      median(x), format = "xx.x"
    ),
    min_max = rcell(
      range(x), format = "xx.x - xx.x"
    ),
    .labels = c("n", "Mean (SD)", "Median", "Min - Max")
  )
}

```

```

lyt <- basic_table() %>%
  split_cols_by("ARM") %>%
  split_rows_by("SEX") %>%
  analyze("AGE", afun = a_summary)

```

	A: Drug X	B: Placebo	C: Combination
F			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
M			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

# Export

rtable object

`build_table(lyt, adsl)`



Title

---

	A: Drug X	B: Placebo	C: Combination
<b>F</b>			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
<b>M</b>			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

Footnotes.

Title

	A: Drug X	B: Placebo	C: Combination
<b>F</b>			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
<b>M</b>			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

Footnotes.

Title

---

	A: Drug X	B: Placebo	C: Combination
<b>F</b>			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
<b>M</b>			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

Footnotes.

Title

	A: Drug X	B: Placebo	C: Combination
<b>F</b>			
n	79	77	66
Mean (SD)	32.8 (6.1)	34.1 (7.1)	35.2 (7.4)
Median	32.0	32.0	35.0
Min - Max	21.0 - 47.0	23.0 - 58.0	21.0 - 64.0
<b>M</b>			
n	51	55	60
Mean (SD)	35.6 (7.1)	37.4 (8.7)	35.4 (8.2)
Median	37.0	37.0	33.5
Min - Max	23.0 - 50.0	21.0 - 62.0	20.0 - 69.0

Footnotes.

docx, pptx via flextable package

# Agenda

01

Overview

02

Basics of rtables

03

**Examples**

04

Using tern

# Examples

- Demographics
- Laboratory Results
- Adverse Events

# Demographics

```
a_summary_num <- function(x) {
  in_rows(
    n = rcell(sum(!is.na(x)), format = "xx"),
    mean_sd = rcell(c(mean(x), sd(x)), format = "xx.x (xx.x)"),
    median = rcell(median(x), format = "xx.x"),
    min_max = rcell(range(x), format = "xx.x - xx.x"),
    .labels = c("n", "Mean (SD)", "Median", "Min - Max")
  )
}
```

[1]

```
a_summary_fct <- function(x, .N_col) {
  in_rows(
    n = rcell(sum(!is.na(x)), format = "xx"),
    .list = as.list(table(x)) %>%
      lapply(function(n) {
        rcell(c(n, n / .N_col), format = "xx (xx.x%)")
      })
  )
}
```

[2]

```
lyt <- basic_table(title = "Demographics", main_footer = " ") %>%
  split_cols_by("ARMCD") %>%
  add_colcounts() %>%
  analyze("AGE", afun = a_summary_num, var_labels = "Age (year)") %>%
  analyze("AGEGR1", afun = a_summary_fct, var_labels = "Age (year)")
```

[3]

```
build_table(lyt, adsl)
```

## Demographics

	ARM A (N=134)	ARM B (N=134)
Age (year)		
n	134	134
Mean (SD)	33.8 (6.6)	35.4 (7.9)
Median	33.0	35.0
Min - Max	21.0 - 50.0	21.0 - 62.0
Age (year)		
n	134	134
< 65	134 (100.0%)	134 (100.0%)
>= 65	0 (0.0%)	0 (0.0%)

# Demographics

```

a_summary_num <- function(x) {
  in_rows(
    n = rcell(
      sum(!is.na(x)), format = "xx"
    ),
    mean_sd = rcell(
      c(mean(x), sd(x)), format = "xx.x (xx.x)"
    ),
    median = rcell(
      median(x), format = "xx.x"
    ),
    min_max = rcell(
      range(x), format = "xx.x - xx.x"
    ),
    .labels = c(
      "n", "Mean (SD)", "Median", "Min - Max"
    )
  )
}

```

[1]

Same as described in previous slide

## Demographics

	ARM A (N=134)	ARM B (N=134)
Age (year)		
n	134	134
Mean (SD)	33.8 (6.6)	35.4 (7.9)
Median	33.0	35.0
Min - Max	21.0 - 50.0	21.0 - 62.0
Age (year)		
n	134	134
< 65	134 (100.0%)	134 (100.0%)
>= 65	0 (0.0%)	0 (0.0%)



# Demographics

```

a_summary_fct <- function(x, .N_col) {
  in_rows(
    n = rcell(sum(!is.na(x)), format = "xx"),
    .list = as.list(table(x)) %>%
      lapply(function(n) { Counts the number of subjects
        rcell(
          c(n, n / .N_col), format = "xx (xx.x%)"
        )
      })
  )
}

```

[2]

Demographics

	ARM A (N=134)	ARM B (N=134)
Age (year)		
n	134	134
Mean (SD)	33.8 (6.6)	35.4 (7.9)
Median	33.0	35.0
Min - Max	21.0 - 50.0	21.0 - 62.0
Age (year)		
n	134	134
< 65	134 (100.0%)	134 (100.0%)
>= 65	0 (0.0%)	0 (0.0%)

# Demographics

```
lyt <- basic_table(
  title = "Demographics",
  main_footer = " "
) %>%
  split_cols_by("ARMCD") %>%
  add_colcounts() %>%
  analyze(
    "AGE",
    afun = a_summary_num,
    var_labels = "Age (year)"
  ) %>%
  analyze(
    "AGEGR1",
    afun = a_summary_fct,
    var_labels = "Age (year)"
  )
```

```
build_table(lyt, adsl)
```

[3]

## Demographics

	ARM A (N=134)	ARM B (N=134)
<b>Age (year)</b>		
n	134	134
Mean (SD)	33.8 (6.6)	35.4 (7.9)
Median	33.0	35.0
Min - Max	21.0 - 50.0	21.0 - 62.0
<b>Age (year)</b>		
n	134	134
< 65	134 (100.0%)	134 (100.0%)
>= 65	0 (0.0%)	0 (0.0%)

# Laboratory Results

```

a_summary_num <- function(x) {
  in_rows(
    n = rcell(sum(!is.na(x)), format = "xx"),
    mean_sd = rcell(c(mean(x), sd(x)), format = "xx.x (xx.x)"),
    median = rcell(median(x), format = "xx.x"),
    min_max = rcell(range(x), format = "xx.x - xx.x"),
    .labels = c("n", "Mean (SD)", "Median", "Min - Max")
  )
}

lyt <- basic_table(title = "Lab Results", main_footer = " ") %>%
  split_cols_by("ARMCD") %>%
  add_colcounts() %>%
  split_rows_by(
    "PARAM", split_fun = drop_split_levels,
    split_label = "Parameter", label_pos = "topleft",
    section_div = ""
  ) %>%
  split_rows_by(
    "AVISIT", split_fun = drop_split_levels,
    split_label = "Visit", label_pos = "topleft",
    section_div = ""
  ) %>%
  analyze("AVAL", afun = a_summary_num)

build_table(lyt, adlb, alt_counts_df = adsl) %>%
  prune_table()

```

## Lab Results

Parameter	ARM A (N=134)	ARM B (N=134)
-----		
Visit		
-----		
Alanine Aminotransferase (U/L)		
BASELINE		
n	134	134
Mean (SD)	49.6 (8.3)	50.3 (8.3)
Median	49.6	50.2
Min - Max	24.0 - 70.9	26.2 - 79.1
WEEK 1 DAY 8		
n	134	134
Mean (SD)	48.6 (8.0)	50.4 (7.9)
Median	48.4	50.2
Min - Max	27.7 - 64.6	21.7 - 67.5
WEEK 2 DAY 15		
n	134	134
Mean (SD)	49.4 (8.5)	50.2 (8.5)
Median	48.3	50.0
Min - Max	24.3 - 71.1	24.4 - 71.1
-----		

# Laboratory Results

```

a_summary_num <- function(x) {
  in_rows(
    n = rcell(
      sum(!is.na(x)), format = "xx"
    ),
    mean_sd = rcell(
      c(mean(x), sd(x)), format = "xx.x (xx.x)"
    ),
    median = rcell(
      median(x), format = "xx.x"
    ),
    min_max = rcell(
      range(x), format = "xx.x - xx.x"
    ),
    .labels = c(
      "n", "Mean (SD)", "Median", "Min - Max"
    )
  )
}

```

Same as described in previous slide

[1]

## Lab Results

---

Parameter	ARM A (N=134)	ARM B (N=134)
-----------	------------------	------------------

---

### Alanine Aminotransferase (U/L)

#### BASELINE

n	134	134
Mean (SD)	49.6 (8.3)	50.3 (8.3)
Median	49.6	50.2
Min - Max	24.0 - 70.9	26.2 - 79.1

#### WEEK 1 DAY 8

n	134	134
Mean (SD)	48.6 (8.0)	50.4 (7.9)
Median	48.4	50.2
Min - Max	27.7 - 64.6	21.7 - 67.5

#### WEEK 2 DAY 15

n	134	134
Mean (SD)	49.4 (8.5)	50.2 (8.5)
Median	48.3	50.0
Min - Max	24.3 - 71.1	24.4 - 71.1

---

# Laboratory Results

```

lyt <- basic_table(
  title = "Lab Results",
  main_footer = " "
) %>%
split_cols_by("ARMCD") %>%
add_colcounts() %>%
split_rows_by(
  "PARAM", split_fun = drop_split_levels,
  split_label = "Parameter", label_pos = "topleft",
  section_div = ""
) %>%
split_rows_by(
  "AVISIT", split_fun = drop_split_levels,
  split_label = "Visit", label_pos = "topleft",
  section_div = ""
) %>%
analyze("AVAL", afun = a_summary_num)

```

[2]

## Lab Results

Parameter	ARM A (N=134)	ARM B (N=134)
Visit		
Alanine Aminotransferase (U/L)		
BASELINE		
n	134	134
Mean (SD)	49.6 (8.3)	50.3 (8.3)
Median	49.6	50.2
Min - Max	24.0 - 70.9	26.2 - 79.1
WEEK 1 DAY 8		
n	134	134
Mean (SD)	48.6 (8.0)	50.4 (7.9)
Median	48.4	50.2
Min - Max	27.7 - 64.6	21.7 - 67.5
WEEK 2 DAY 15		
n	134	134
Mean (SD)	49.4 (8.5)	50.2 (8.5)
Median	48.3	50.0
Min - Max	24.3 - 71.1	24.4 - 71.1

# Laboratory Results

```
build_table(
  lyt,
  adlb, Uses adsl for column count
  alt_counts_df = adsl
) %>% prune_table()
Removes if the subset is empty
```

[3]

## Lab Results

Parameter	ARM A	ARM B
Visit	(N=134)	(N=134)
Alanine Aminotransferase (U/L)		
BASELINE		
n	134	134
Mean (SD)	49.6 (8.3)	50.3 (8.3)
Median	49.6	50.2
Min - Max	24.0 - 70.9	26.2 - 79.1
WEEK 1 DAY 8		
n	134	134
Mean (SD)	48.6 (8.0)	50.4 (7.9)
Median	48.4	50.2
Min - Max	27.7 - 64.6	21.7 - 67.5
WEEK 2 DAY 15		
n	134	134
Mean (SD)	49.4 (8.5)	50.2 (8.5)
Median	48.3	50.0
Min - Max	24.3 - 71.1	24.4 - 71.1

# Adverse Events

```

a_num_patients <- function(x, labelstr, .N_col) {
  n <- length(unique(x))
  in_rows(
    unique = rcell(c(n, n / .N_col), format = "xx (xx.x%)"),
    nonunique = rcell(length(x), format = "xx"),
    .labels = c(
      unique = "Total number of pts with at least one AE",
      nonunique = "Total number of events"
    )
  )
}

a_count_occ <- function(df, .var, .N_col) {
  counts <- table(unique(df[, c(.var, "USUBJID")])[[.var]])
  in_rows(
    .list = as.list(counts) %>%
      lapply(function(n) {
        rcell(c(n, n / .N_col), format = "xx (xx.x%)")
      })
  )
}

lyt <- basic_table(
  title = "Adverse events",
  main_footer = "MedDRA version xx.x"
) %>%
  split_cols_by("ARMCD") %>%
  add_colcounts() %>%
  analyze("USUBJID", afun = a_num_patients) %>%
  split_rows_by(
    "AEBODSYS",
    split_label = "System Organ Class",
    label_pos = "topleft",
    child_labels = "visible"
  ) %>%
  summarize_row_groups("USUBJID", cfun = a_num_patients) %>%
  analyze("AEDECOD", afun = a_count_occ, indent_mod = -1) %>%
  append_topleft(" Preferred Term")

build_table(lyt, adae, alt_counts_df = ads1) %>%
  prune_table()

```

[1]

[2]

[3]

## Adverse events

System Organ Class Preferred Term	ARM A (N=134)	ARM B (N=134)
Total number of pts with at least one AE	102 (76.1%)	99 (73.9%)
Total number of events	261	268
c1 A.1		
Total number of pts with at least one AE	78 (58.2%)	75 (56.0%)
Total number of events	132	130
dcd A.1.1.1.1	50 (37.3%)	45 (33.6%)
dcd A.1.1.1.2	48 (35.8%)	48 (35.8%)
c1 B.2		
Total number of pts with at least one AE	79 (59.0%)	74 (55.2%)
Total number of events	129	138
dcd B.2.1.2.1	49 (36.6%)	44 (32.8%)
dcd B.2.2.3.1	48 (35.8%)	54 (40.3%)

MedDRA version xx.x

# Adverse Events

```

lyt <- basic_table(
  title = "Adverse events",
  main_footer = "MedDRA version xx.x"
) %>%
  split_cols_by("ARMCD") %>%
  add_colcounts() %>%
  analyze("USUBJID", afun = a_num_patients) %>%
  split_rows_by(
    "AEBODSYS",
    split_label = "System Organ Class",
    label_pos = "topleft",
    child_labels = "visible"
  ) %>%
  summarize_row_groups("USUBJID", cfun = a_num_patients) %>%
  analyze(
    "AEDECOD",
    afun = a_count_occ,
    indent_mod = -1
  ) %>%
  append_topleft(" Preferred Term")

build_table(lyt, adae, alt_counts_df = adsl) %>%
  prune_table()

```

[3]

Adverse events

System Organ Class Preferred Term	ARM A (N=134)	ARM B (N=134)
Total number of pts with at least one AE	102 (76.1%)	99 (73.9%)
Total number of events	261	268
c1 A.1		
Total number of pts with at least one AE	78 (58.2%)	75 (56.0%)
Total number of events	132	130
dcd A.1.1.1.1	50 (37.3%)	45 (33.6%)
dcd A.1.1.1.2	48 (35.8%)	48 (35.8%)
c1 B.2		
Total number of pts with at least one AE	79 (59.0%)	74 (55.2%)
Total number of events	129	138
dcd B.2.1.2.1	49 (36.6%)	44 (32.8%)
dcd B.2.2.3.1	48 (35.8%)	54 (40.3%)

MedDRA version xx.x



# Adverse Events

```

a_num_patients <- function(x, labelstr, .N_col) {
  n <- length(unique(x))
  in_rows(
    unique = rcell(
      c(n, n / .N_col),
      format = "xx (xx.x%)"
    ),
    nonunique = rcell(
      length(x),
      format = "xx"
    ),
    .labels = c(
      unique = "Total number of pts with at least one AE",
      nonunique = "Total number of events"
    )
  )
}

```

[1]

Adverse events

System Organ Class Preferred Term	ARM A (N=134)	ARM B (N=134)
Total number of pts with at least one AE	102 (76.1%)	99 (73.9%)
Total number of events	261	268
c1 A.1		
Total number of pts with at least one AE	78 (58.2%)	75 (56.0%)
Total number of events	132	130
dcd A.1.1.1.1	50 (37.3%)	45 (33.6%)
dcd A.1.1.1.2	48 (35.8%)	48 (35.8%)
c1 B.2		
Total number of pts with at least one AE	79 (59.0%)	74 (55.2%)
Total number of events	129	138
dcd B.2.1.2.1	49 (36.6%)	44 (32.8%)
dcd B.2.2.3.1	48 (35.8%)	54 (40.3%)

MedDRA version xx.x

# Adverse Events

```

a_count_occ <- function(df, .var, .N_col) {
  counts <- table(unique(df[, c(.var, "USUBJID")])[[.var]])
  in_rows(
    .list = as.list(counts) %>%
      lapply(function(n) {
        rcell(c(n, n / .N_col), format = "xx (xx.x%)")
      })
  )
}

```

Adverse events

System Organ Class Preferred Term	ARM A (N=134)	ARM B (N=134)
Total number of pts with at least one AE	102 (76.1%)	99 (73.9%)
Total number of events	261	268
c1 A.1		
Total number of pts with at least one AE	78 (58.2%)	75 (56.0%)
Total number of events	132	130
dcd A.1.1.1.1	50 (37.3%)	45 (33.6%)
dcd A.1.1.1.2	48 (35.8%)	48 (35.8%)
c1 B.2		
Total number of pts with at least one AE	79 (59.0%)	74 (55.2%)
Total number of events	129	138
dcd B.2.1.2.1	49 (36.6%)	44 (32.8%)
dcd B.2.2.3.1	48 (35.8%)	54 (40.3%)

MedDRA version xx.x

# Agenda

01

Overview

02

Basics of rtables

03

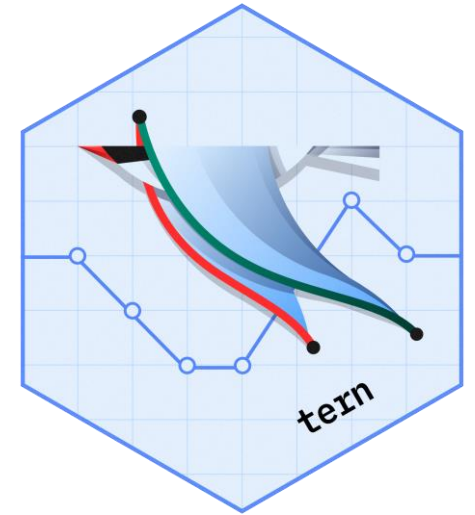
Examples

04

**Using tern**

# tern

- R package contains analysis functions to create tables and graphs used for clinical trial reporting.
- Built on top of rtables package.
- Complicated rtables codes are represented more simple and easy to understand using tern.
- Open source (Apache License, Version 2.0)



# Demographics using tern

```
lyt <- basic_table(
  title = "Demographics",
  main_footer = " "
) %>%
  split_cols_by("ARMCD") %>%
  add_colcounts() %>%
  analyze_vars(
    "AGE",
    var_labels = "Age (year)",
    .stats = c("n", "mean_sd", "median", "range")
  ) %>%
  analyze_vars(
    "AGEGR1",
    var_labels = "Age (year)",
    .stats = c("n", "count_fraction")
  )
build_table(lyt, adsl)
```

tern function

tern function

## Demographics

	ARM A (N=134)	ARM B (N=134)
<b>Age (year)</b>		
n	134	134
Mean (SD)	33.8 (6.6)	35.4 (7.9)
Median	33.0	35.0
Min - Max	21.0 - 50.0	21.0 - 62.0
<b>Age (year)</b>		
n	134	134
< 65	134 (100.0%)	134 (100.0%)
>= 65	0 (0.0%)	0 (0.0%)

# Adverse Events using tern

```
lyt <- basic_table(
  title = "Adverse events",
  main_footer = "MedDRA version xx.x"
) %>%
  split_cols_by("ARMCD") %>%
  add_colcounts() %>%
  analyze_num_patients(
    "USUBJID",
    .stats = c("unique", "nonunique"),
    .labels = c(
      unique = "Total number of pts with at least one AE",
      nonunique = "Total number of events"
    )
  ) %>%
  split_rows_by(
    "AEBODSYS",
    split_label = "System Organ Class",
    label_pos = "topleft",
    child_labels = "visible"
  ) %>%
  summarize_num_patients(
    "USUBJID",
    .stats = c("unique", "nonunique"),
    .labels = c(
      unique = "Total number of pts with at least one AE",
      nonunique = "Total number of events"
    )
  ) %>%
  count_occurrences("AEDECOD", .indent_mods = -1L) %>%
  append_topleft(" Preferred Term")
  tern function

build_table(lyt, adae, alt_counts_df = adsl) %>%
  prune_table()
```

## Adverse events

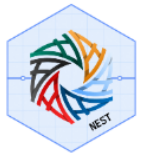
System Organ Class Preferred Term	ARM A (N=134)	ARM B (N=134)
Total number of pts with at least one AE	102 (76.1%)	99 (73.9%)
Total number of events	261	268
c1 A.1		
Total number of pts with at least one AE	78 (58.2%)	75 (56.0%)
Total number of events	132	130
dcd A.1.1.1.1	50 (37.3%)	45 (33.6%)
dcd A.1.1.1.2	48 (35.8%)	48 (35.8%)
c1 B.2		
Total number of pts with at least one AE	79 (59.0%)	74 (55.2%)
Total number of events	129	138
dcd B.2.1.2.1	49 (36.6%)	44 (32.8%)
dcd B.2.2.3.1	48 (35.8%)	54 (40.3%)

MedDRA version xx.x

# TLG Catalog

TLG Catalog - Stable

Stable



## DMT01

Demographics and Baseline Characteristics

[Data Setup](#)
[Table with an Additional Study-Specific Continuous Variable](#)
[Table with an Additional Study-Specific Categorical Variable](#)
[Table with Subgrouping for Some Analyses](#)

[Table with Additional Vital Signs Baseline Values](#)
[Table with Additional Values from ADSUB](#)
[tea1 App](#)
[Reproducibility](#)

```

Code
1 vars <- c("AGE", "AGEGR1", "SEX", "ETHNIC", "RACE", "BMRKR1")
2 var_labels <- c(
3   "Age (yr)",
4   "Age Group",
5   "Sex",
6   "Ethnicity",
7   "Race",
8   "Continuous Level Biomarker 1"
9 )
10
11 result <- basic_table(show_colcounts = TRUE) %>%
12   split_cols_by(var = "ACTARM") %>%
13   add_overall_col("All Patients") %>%
14   analyze_vars(
15     vars = vars,
16     var_labels = var_labels
17   ) %>%
18   build_table(ads1)
19
20 result
    
```

	A: Drug X (N=134)	B: Placebo (N=134)	C: Combination (N=132)	All Patients (N=400)
Age (yr)				
n	134	134	132	400
Mean (SD)	33.8 (6.6)	35.4 (7.9)	35.4 (7.7)	34.9 (7.4)
Median	33.0	35.0	35.0	34.0
Min - Max	21.0 - 50.0	21.0 - 62.0	20.0 - 69.0	20.0 - 69.0
Age Group				
n	134	134	132	400
18-40	113 (84.3%)	103 (76.9%)	106 (80.3%)	322 (80.5%)
41-64	21 (15.7%)	31 (23.1%)	25 (18.9%)	77 (19.2%)
>=65	0	0	1 (0.8%)	1 (0.2%)
Sex				
n	134	134	132	400
Female	79 (59%)	82 (61.2%)	70 (53%)	231 (57.8%)
Male	55 (41%)	52 (38.8%)	62 (47%)	169 (42.2%)
Ethnicity				
n	134	134	132	400
NOT REPORTED	6 (4.5%)	10 (7.5%)	11 (8.3%)	27 (6.8%)
HISPANIC OR LATINO	15 (11.2%)	18 (13.4%)	15 (11.4%)	48 (12%)
NOT HISPANIC OR LATINO	104 (77.6%)	103 (76.9%)	101 (76.5%)	308 (77%)



# Impression

- **Easy to design table layouts**
  - Basically, defined as column splits and row splits
- **Easy to define analysis functions.**
  - Receives subset data
  - Separated from table layout
- **Difficult to make tables that deviates from the pattern composed by column and row splits.**
- **Analysis functions tend to be complicated**
  - Use tern package



# INNOVATION BEYOND IMAGINATION